Rev 09/09

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application	:	Lars I.E. Oddsson et al.
Application No.	:	10/511,023
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For	:	SENSOR PROSTHETIC FOR IMPROVED BALANCE CONTROL
Examiner	:	Fangemonique A. Smith
Attorney's Docket	:	BU-082XX

TC Art Unit: 3736

* *

AFFIDAVIT OF PETER F. MEYER
UNDER 37 C.F.R. § 1.131

Via Electronic Filing
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, PETER F. MEYER, hereby declare that:

1. I am a co-inventor of the claimed subject matter of the above-identified United States patent application, in which claims 2-4, 15-19, 21, 25-27, 30-37, 71, and 72 stand rejected under 35 USC § 103(a) as unpatentable over U.S. Patent Number 7,403,821 to Haugland, et al. ("Haugland") in view of U.S. Patent Number 6,063,046 to Allum ("Allum") and claims 5-10 and claim 20 stand rejected under 35 USC § 103(a) as unpatentable over Haugland and Allum, further in view of U.S. Patent Number 6,174,294 to Crabb, et al. ("Crabb") in an Official Action dated November 25, 2009.

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2. I have read the specification and claims of the above-identified patent application, the Official Action, and the Haugland, Allum, and Crabb references.

3. My co-inventor, Lars I.E. Oddsson and I conceived of and reduced to practice in the United States the subject matter encompassed by claims 2-10, 15-21, 25-27, 30-37, 71, and 72 pending in the instant patent application prior to August 23, 2001 which is the publication date of International Patent Application Number PCT/DK2001/00112 from which Haugland claims priority.

4. On March 24, 2000 a PC-based prototype of the invention as claimed was reduced to practice in the United States. Enclosed as Exhibit A is a true and accurate copy of an application for funding that shows the "[f]irst prototype of sensory substitution device" and a constructive reduction to practice of a second, wearable and portable, microprocessor-based embodiment of the device in Figure 1 on page 5 of Exhibit A. Upon my best knowledge and belief the date of the application was on or about February 15, 2001.

More specifically, with respect to and quoting from independent claim 71, "a system for assisting the maintenance of balance over time during standing and gait of a user" is disclosed on page 2 in section a (i.e., "a plan to build a sensory

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substitution device to be worn by individuals with balance problems related to altered foot pressure sensation"); "a sensing layer adapted for user wearing under a user's foot during conditions of standing and gait, said layer having a plurality of sensors positioned for sensing two dimensional force distribution under said user's foot" is shown in Figure 1 on page 5 and is further disclosed on pages 4-5 in section c.2 (i.e., "the device consists of a series of pressure sensors that are placed at specific location under the feet"); "excitation means for said sensors which, during user standing and gait, provide signals representing user balance information as a function of said two dimensional force distribution over time" is shown in Figure 1 on page 5 and is further disclosed on pages 4-5 in section c.2 (i.e., "The results of these [pressure signal] calculations are used to drive 16 digital outputs on the A/D card that in turn activate eight small vibrators placed around the lower legs of the subject"); "said sensing layer adapted to transmit said balance information signals to a remote location under conditions of standing and gait" is disclosed on page 5 in section c.2 (i.e., "signals are acquired by a PC with a special A/D card"); "a signal processing subsystem at said remote location and adapted to be user wearable, said subsystem configured to receive said balance

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information signals and to provide in response thereto balance control signals containing temporal and spatial information reflecting said force distribution for use in user skin stimulation" is shown attached to the calf in Figure 1 ("Second generation [microprocessor controller] device will include portable controller") and is further disclosed on page 5 in section c.2 (i.e., "The results of these [pressure signal] calculations are used to drive 16 digital outputs on the A/D card that in turn activate eight small horizontally and vertically displaced vibrators placed around the lower legs of the subject"); "an array of a plurality of stimulators adapted for attachment in contact with a skin area of said user" is shown in Figure 1 on page 5 and is further disclosed on page 5 in section c.2 (i.e., "eight small vibrators placed around the lower legs of the subject"); and "said plurality of stimulators arranged in a two dimensional array and responsive to said balance control signals to provide skin stimulation to said user in a form reflecting said two dimensional force distribution under said user's foot both spatially and temporally in said two dimensional force distribution over time, both under conditions of standing and gait, to thereby provide feedback to the user via the array of plural stimulators to provide individualized spatial mapping and

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temporal information to allow complex, multi-dimensional and time varying corrective action" is disclosed on page 5 in section c.2 (i.e., "The subject is instructed to use the vibrations as an indicator of upright body position. When the subject is standing upright, the vibrations will decrease. Increased sway in a certain direction will increase the vibration on the same side of the leg as the direction of the sway.").

With respect to and quoting from independent claim 72, a "system for assisting the maintenance of balance over time during standing and gait of a user" is disclosed on page 2 in section a (i.e., "a plan to build a sensory substitution device to be worn by individuals with balance problems related to altered foot pressure sensation"); "a sensing layer adapted for user wearing under a user's foot during conditions of standing and gait, said layer having a plurality of sensors positioned for sensing two dimensional force distribution under said user's foot is shown in Figure 1 on page 5 and is further disclosed on pages 4-5 in section c.2 (i.e., "the device consists of a series of pressure sensors that are placed at specific location under the feet"); "excitation means for said sensors which, during user standing and gait, provide signals representing user balance information as a function of said two dimensional force distribution over time" is

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shown in Figure 1 on page 5 and is further disclosed on pages 4-5 in section c.2 (i.e., "The results of these [pressure signal] calculations are used to drive 16 digital outputs on the A/D card that in turn activate eight small vibrators placed around the lower legs of the subject"); "said sensing layer adapted to transmit said balance information signals to a remote location under conditions of standing and gait" is disclosed on page 5 in section c.2 (i.e., "signals are acquired by a PC with a special A/D card"); "a signal processing subsystem at said remote location and adapted to be user wearable, said subsystem configured to receive said balance information signals and to provide in response thereto balance control signals containing temporal and spatial information reflecting said force distribution for use in user skin stimulation is shown attached to the calf in Figure 1 ("Second generation [microprocessor controller] device will include portable controller") and is further disclosed on page 5 in section c.2 (i.e., "The results of these [pressure signal] calculations are used to drive 16 digital outputs on the A/D card that in turn activate eight small vibrators placed around the lower legs of the subject"); "an array of a plurality of stimulators adapted for attachment in contact with a skin area of said user" is shown in Figure 1 on page 5 and is further disclosed

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on page 5 in section c.2 (i.e., "eight small vibrators placed around the lower legs of the subject"); and "said plurality of stimulators responsive to said balance control signals to provide skin stimulation to said user in a form reflecting said two dimensional force distribution under said user's foot both spatially and temporally in said balance control signals to provide skin stimulation to said user reflecting said two dimensional force distribution changes over time both under conditions of standing and gait, to thereby provide feedback to the user via the array of plural stimulators to provide individualized spatial mapping and temporal information to allow complex, multi-dimensional and time varying corrective action" is disclosed on page 5 in section c.2 (i.e., "The subject is instructed to use the vibrations as an indicator of upright body position. When the subject is standing upright, the vibrations will decrease. Increased sway in a certain direction will increase the vibration on the same side of the leg as the direction of the sway.").

5. Enclosed as Exhibit B is a true and accurate copy of an embodiment of a Sensory Prosthetic for Improved Balance Control dated May 11, 2000. In pertinent part, Exhibit B recites that the "[s]ensor array may be incorporated into a shoe or implemented as

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a shoe insert", which is to say that the invention as claimed was meant to be worn. The Sensory Prosthetic for Improved Balance Control dated May 11, 2000 shown as Exhibit B is identical or virtually identical to the wearable and portable, microprocessor-based embodiment of the device in Figure 1 on page 5 of Exhibit A.

More specifically, with respect to and quoting from independent claim 71 "a system for assisting the maintenance of balance over time during standing and gait of a user" is provided in the title (i.e., "Sensory Prosthetic for Improved Balance Control") and in the Uses section (i.e., "Improving static [i.e., standing] and dynamic [i.e., during gait] balance control"); "a sensing layer adapted for user wearing under a user's foot during conditions of standing and gait, said layer having a plurality of sensors positioned for sensing two dimensional force distribution under said user's foot" is shown in the figure as the Plantar Pressure Sensor Array, which "transduces pressure distribution under the foot and transfers that information to the Signal Processor/Controller"; "excitation means for said sensors which, during user standing and gait, provide signals representing user balance information as a function of said two dimensional force distribution over time" is shown in the Figure as the "Feedback Array (i.e., "Vibrotactile or electrotactile cutaneous feedback);

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"said sensing layer adapted to transmit said balance information signals to a remote location under conditions of standing and gait" is shown in the figure as the Plantar Pressure Sensor Array, which "transduces pressure distribution under the foot and transfers that information to the Signal Processor/Controller"; "a signal processing subsystem at said remote location and adapted to be user wearable, said subsystem configured to receive said balance information signals and to provide in response thereto balance control signals containing temporal and spatial information reflecting said force distribution for use in user skin stimulation" is shown in the figure as the Signal Processor/Controller, which is attached to the calf, that "Converts electrical or mechanical signal(s) from Plantar Pressure Sensor Array into signal(s) which control the activity of the Feedback Array element(s)"; "an array of a plurality of stimulators adapted for attachment in contact with a skin area of said user" is shown as the Feedback Array in the figure, which "is located adjacent the skin of the leg or thigh"; and "said plurality of stimulators arranged in a two dimensional array and responsive to said balance control signals to provide skin stimulation to said user in a form reflecting said two dimensional force distribution under said user's foot both spatially and

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temporally in said two dimensional force distribution over time, both under conditions of standing and gait, to thereby provide feedback to the user via the array of plural stimulators to provide individualized spatial mapping and temporal information to allow complex, multi-dimensional and time varying corrective action" is shown in the figure as the Feedback Array, which "encodes position of foot Center-of-Pressure and/or weight distribution by modulating one or more of the following: stimulus frequency, stimulus amplitude, location of stimulus or number of active stimulators. . . The location of active stimulator(s) on the skin in the transverse plane will directly reflect the location of the foot Center-of-Pressure in the transverse plane.".

With respect to and quoting from independent claim 72, a "system for assisting the maintenance of balance over time during standing and gait of a user" is provided in the title (i.e., "Sensory Prosthetic for Improved Balance Control") and in the Uses section (i.e., "Improving static [i.e., standing] and dynamic [i.e., during gait] balance control"); "a sensing layer adapted for user wearing under a user's foot during conditions of standing and gait, said layer having a plurality of sensors positioned for sensing two dimensional force distribution under said user's foot" is shown in the figure as the Plantar Pressure Sensor Array, which

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"transduces pressure distribution under the foot and transfers that information to the Signal Processor/Controller"; "excitation means for said sensors which, during user standing and gait, provide signals representing user balance information as a function of said two dimensional force distribution over time" is shown in the Figure as the "Feedback Array (i.e., "Vibrotactile or electrotactile cutaneous feedback); "said sensing layer adapted to transmit said balance information signals to a remote location under conditions of standing and gait" is shown in the figure as the Plantar Pressure Sensor Array, which "transduces pressure distribution under the foot and transfers that information to the Signal Processor/Controller"; "a signal processing subsystem at said remote location and adapted to be user wearable, said subsystem configured to receive said balance information signals and to provide in response thereto balance control signals containing temporal and spatial information reflecting said force distribution for use in user skin stimulation is shown in the figure as the Signal Processor/Controller, which is attached to the calf, that "Converts electrical or mechanical signal(s) from Plantar Pressure Sensor Array into signal(s) which control the activity of the Feedback Array element(s)"; "an array of a plurality of stimulators adapted for attachment in contact with a

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skin area of said user" is shown as the Feedback Array in the figure, which "is located adjacent the skin of the leg or thigh"; and "said plurality of stimulators responsive to said balance control signals to provide skin stimulation to said user in a form reflecting said two dimensional force distribution under said user's foot both spatially and temporally in said balance control signals to provide skin stimulation to said user reflecting said two dimensional force distribution changes over time both under conditions of standing and gait, to thereby provide feedback to the user via the array of plural stimulators to provide individualized spatial mapping and temporal information to allow complex, multi-dimensional and time varying corrective action" is shown in the figure as the Feedback Array, which "encodes position of foot Center-of-Pressure and/or weight distribution by modulating one or more of the following: stimulus frequency, stimulus amplitude, location of stimulus or number of active stimulators. . . The location of active stimulator(s) on the skin in the transverse plane will directly reflect the location of the foot Center-of-Pressure in the transverse plane".

6. Enclosed as Exhibit C is a true and accurate copy of a report of testing results published in February 2001 for the PC-based prototype reduced to practice on March 24, 2000. More

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specifically, with respect to independent claim 71 "a system for assisting the maintenance of balance over time during standing and gait of a user" is provided in the "Introduction" section on page 1 (i.e., "The object of this project was to investigate the potential of a prototype foot-sole pressure sensory substitution system to increase postural stability in healthy subjects without postural deficiencies."); "a sensing layer adapted for user wearing under a user's foot during conditions of standing and gait, said layer having a plurality of sensors positioned for sensing two dimensional force distribution under said user's foot" is shown in Figure 6 on page 8 and is further disclosed on pages 8 and 9 (i.e., "Seven of these [force sensing resistor] transducers were arranged in a matrix according to the location of seven prominent bones in the subject's foot: the large toe, the 1st, 2nd, 3rd, and 4th metatarsal heads, the inferior medial navicular, and the calcaneus midline"); "excitation means for said sensors which, during user standing and gait, provide signals representing user balance information as a function of said two dimensional force distribution over time" is disclosed on pages 9 and 10 (i.e., "Each vibrator array consisted of four vibrators associated with the anterior, posterior, medial, and lateral directions of the foot sole. . . . Once one of the COP displacements under the

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feet exceeded the threshold, the subject received vibration on the corresponding leg in the direction of the displacement."); "said sensing layer adapted to transmit said balance information signals to a remote location under conditions of standing and gait" is disclosed on page 9 (i.e., "The FSR Amplifier Unit generated these force-controlled voltage signals for each FSR in the matrices. These output voltage signals were then sampled by the 14 analog input channels on the MicroStar Laboratories 2400 Data Acquisition Processor (DAP) card."); "a signal processing subsystem at said remote location and adapted to be user wearable, said subsystem configured to receive said balance information signals and to provide in response thereto balance control signals containing temporal and spatial information reflecting said force distribution for use in user skin stimulation" is disclosed on page 9 (i.e., "The average positions of the COP under each of the subject's feet were calculated . . . then entered into the feedback program and used as the reference positions for calculating the individual foot COP displacements during feedback. These estimated COP trajectories were then used to activate the vibrator arrays on the right and left legs."); "an array of a plurality of stimulators adapted for attachment in contact with a skin area of said user" is disclosed on page 9 (i.e., "The

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vibrators were circumferentially positioned around the subject's upper calves, facing in the directions to which they corresponded."); and "said plurality of stimulators arranged in a two dimensional array and responsive to said balance control signals to provide skin stimulation to said user in a form reflecting said two dimensional force distribution under said user's foot both spatially and temporally in said two dimensional force distribution over time, both under conditions of standing and gait, to thereby provide feedback to the user via the array of plural stimulators to provide individualized spatial mapping and temporal information to allow complex, multi-dimensional and time varying corrective action" is disclosed on pages 9 and 10 (i.e., "Each vibrator array consisted of four vibrators associated with the anterior, posterior, medial, and lateral directions of the foot sole. . . Once one of the COP displacements under the feet exceeded the threshold, the subject received vibration on the corresponding leg in the direction of the displacement.").

With respect to and quoting from independent claim 72, a "system for assisting the maintenance of balance over time during standing and gait of a user" is provided in the "Introduction" section on page 1 (i.e., "The object of this project was to investigate the potential of a prototype foot-sole pressure

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sensory substitution system to increase postural stability in healthy subjects without postural deficiencies."); "a sensing layer adapted for user wearing under a user's foot during conditions of standing and gait, said layer having a plurality of sensors positioned for sensing two dimensional force distribution under said user's foot" is shown in Figure 6 on page 8 and is further disclosed on pages 8 and 9 (i.e., "Seven of these [force sensing resistor] transducers were arranged in a matrix according to the location of seven prominent bones in the subject's foot: the large toe, the 1^{st}, 2^{nd}, 3^{rd}, and 4^{th} metatarsal heads, the inferior medial navicular, and the calcaneus midline"); "excitation means for said sensors which, during user standing and gait, provide signals representing user balance information as a function of said two dimensional force distribution over time" is disclosed on pages 9 and 10 (i.e., "Each vibrator array consisted of four vibrators associated with the anterior, posterior, medial, and lateral directions of the foot sole. . . Once one of the COP displacements under the feet exceeded the threshold, the subject received vibration on the corresponding leg in the direction of the displacement."); "said sensing layer adapted to transmit said balance information signals to a remote location under conditions of standing and gait" is disclosed on page 9 (i.e., "The FSR

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Amplifier Unit generated these force-controlled voltage signals for each FSR in the matrices. These output voltage signals were then sampled by the 14 analog input channels on the MicroStar Laboratories 2400 Data Acquisition Processor (DAP) card."); "a signal processing subsystem at said remote location and adapted to be user wearable, said subsystem configured to receive said balance information signals and to provide in response thereto balance control signals containing temporal and spatial information reflecting said force distribution for use in user skin stimulation" is disclosed on page 9 (i.e., "The average positions of the COP under each of the subject's feet were calculated . . . then entered into the feedback program and used as the reference positions for calculating the individual foot COP displacements during feedback. These estimated COP trajectories were then used to activate the vibrator arrays on the right and left legs."); "an array of a plurality of stimulators adapted for attachment in contact with a skin area of said user" is disclosed on page 9 (i.e., "The vibrators were circumferentially positioned around the subject's upper calves, facing in the directions to which they corresponded."); and "said plurality of stimulators responsive to said balance control signals to provide skin stimulation to said user in a form reflecting said two dimensional

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force distribution under said user's foot both spatially and temporally in said balance control signals to provide skin stimulation to said user reflecting said two dimensional force distribution changes over time both under conditions of standing and gait, to thereby provide feedback to the user via the array of plural stimulators to provide individualized spatial mapping and temporal information to allow complex, multi-dimensional and time varying corrective action" is disclosed on pages 9 and 10 (i.e., "Each vibrator array consisted of four vibrators associated with the anterior, posterior, medial, and lateral directions of the foot sole. . . Once one of the COP displacements under the feet exceeded the threshold, the subject received vibration on the corresponding leg in the direction of the displacement.").

7. Enclosed as Exhibit D are true and accurate copies of an enabling disclosure of the invention as claimed submitted to the Technology Transfer Office of Boston University on or about October 23, 2000 and a Boston University Technology Disclosure Form. Upon my best knowledge and belief, the invention as claimed was assigned Boston University case number BU-00-67 on or about October 23, 2000. In pertinent part, the Boston University Technology Disclosure form documents the March 24, 2000 actual reduction to practice date; shows the constructive reduction to

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practice of the wearable and portable, microprocessor-based embodiment of the device in Figure 1 on page 5 of Exhibit A; and discloses that the invention as claimed "measures information related to the balance of a person while walking or standing" (Introduction, page 1).

More specifically, with respect to and quoting from independent claim 71, "a system for assisting the maintenance of balance over time during standing and gait of a user" is disclosed on page 1 in the Introduction section (i.e., "A portable feedback device is disclosed which measures information related to the balance of a person while walking or standing and produces stimulation of the skin that encodes that information"); "a sensing layer adapted for user wearing under a user's foot during conditions of standing and gait, said layer having a plurality of sensors positioned for sensing two dimensional force distribution under said user's foot" is disclosed on page 1 in the "Description of the Device" section (i.e., "An array sensor arranged under the soles of each foot which transduces the magnitude of pressure exerted on the foot sole at each sensor location"); "excitation means for said sensors which, during user standing and gait, provide signals representing user balance information as a function of said two dimensional force distribution over time" is

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disclosed on page 2 in the "Description of the Device" section (i.e., "An array of vibrotactile stimulators that are placed upon the leg in a plane approximately parallel to the plane of the foot sole in four locations on each leg. . . In response to signals produced by the signal processor, the array provides vibrotactile stimulation of the skin of the leg."); "said sensing layer adapted to transmit said balance information signals to a remote location under conditions of standing and gait" is disclosed on page 21 in the "State of Development" section (i.e., "In the current implementation, normal pressure from each FSR [force-sensing resistor] obtained through the FSR Amplification Unit. These signals are acquired by the DAP [data acquisition processor) and used the estimate the location of the Center-of-Pressure under each foot in real time."); "a signal processing subsystem at said remote location and adapted to be user wearable, said subsystem configured to receive said balance information signals and to provide in response thereto balance control signals containing temporal and spatial information reflecting said force distribution for use in user skin stimulation" is disclosed on page 21 in the "State of Development" section (i.e., "A computer algorithm uses this [Center-or-Pressure] information to select and modulate the frequency of the appropriate vibrator on the

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ipsilateral limb. The feedback signals are sent to the vibrators via the Feedback Amplification Unit, producing localized vibration of the skin of the leg."); "an array of a plurality of stimulators adapted for attachment in contact with a skin area of said user" is disclosed on page 21 in the "State of Development" section (i.e., "The feedback signals are sent to the vibrators via the Feedback Amplification Unit, producing localized vibration of the skin of the leg."); and "said plurality of stimulators arranged in a two dimensional array and responsive to said balance control signals to provide skin stimulation to said user in a form reflecting said two dimensional force distribution under said user's foot both spatially and temporally in said two dimensional force distribution over time, both under conditions of standing and gait, to thereby provide feedback to the user via the array of plural stimulators to provide individualized spatial mapping and temporal information to allow complex, multi-dimensional and time varying corrective action" is disclosed on page 21 in the "State of Development" section (i.e., "A computer algorithm uses this [Center-or-Pressure] information to select and modulate the frequency of the appropriate vibrator on the ipsilateral limb. The feedback signals are sent to the vibrators via the Feedback

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Amplification Unit, producing localized vibration of the skin of the leg.").

With respect to and quoting from independent claim 72, a "system for assisting the maintenance of balance over time during standing and gait of a user" is disclosed on page 1 in the "Introduction" section (i.e., "A portable feedback device is disclosed which measures information related to the balance of a person while walking or standing and produces stimulation of the skin that encodes that information"); "a sensing layer adapted for user wearing under a user's foot during conditions of standing and gait, said layer having a plurality of sensors positioned for sensing two dimensional force distribution under said user's foot" is disclosed on page 1 in the "Description of the Device" section (i.e., "An array sensor arranged under the soles of each foot which transduces the magnitude of pressure exerted on the foot sole at each sensor location"); "excitation means for said sensors which, during user standing and gait, provide signals representing user balance information as a function of said two dimensional force distribution over time" is disclosed on page 2 in the "Description of the Device" section (i.e., "An array of vibrotactile stimulators that are placed upon the leg in a plane approximately parallel to the plane of the foot sole in four

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locations on each leg. . . In response to signals produced by the signal processor, the array provides vibrotactile stimulation of the skin of the leg."); "said sensing layer adapted to transmit said balance information signals to a remote location under conditions of standing and gait" is disclosed on page 21 in the "State of Development" section (i.e., "In the current implementation, normal pressure from each FSR [force-sensing resistor] [is] obtained through the FSR Amplification Unit. These signals are acquired by the DAP [data acquisition processor) and used the estimate the location of the Center-of-Pressure under each foot in real time."); "a signal processing subsystem at said remote location and adapted to be user wearable, said subsystem configured to receive said balance information signals and to provide in response thereto balance control signals containing temporal and spatial information reflecting said force distribution for use in user skin stimulation" is disclosed on page 21 in the "State of Development" section (i.e., "A computer algorithm uses this [Center-or-Pressure] information to select and modulate the frequency of the appropriate vibrator on the ipsilateral limb. The feedback signals are sent to the vibrators via the Feedback Amplification Unit, producing localized vibration of the skin of the leg."); "an array of a plurality of stimulators

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adapted for attachment in contact with a skin area of said user" is disclosed on page 2 in the "Description of the Device" section (i.e., "An array of vibrotactile stimulators that are placed upon the leg in a plane approximately parallel to the plane of the foot sole in four locations on each leg. . . In response to signals produced by the signal processor, the array provides vibrotactile stimulation of the skin of the leg."); and "said plurality of stimulators responsive to said balance control signals to provide skin stimulation to said user in a form reflecting said two dimensional force distribution under said user's foot both spatially and temporally in said balance control signals to provide skin stimulation to said user reflecting said two dimensional force distribution changes over time both under conditions of standing and gait, to thereby provide feedback to the user via the array of plural stimulators to provide individualized spatial mapping and temporal information to allow complex, multi-dimensional and time varying corrective action" is disclosed on page 21 in the "State of Development" section (i.e., "A computer algorithm uses this [Center-or-Pressure] information to select and modulate the frequency of the appropriate vibrator on the ipsilateral limb. The feedback signals are sent to the

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vibrators via the Feedback Amplification Unit, producing localized vibration of the skin of the leg.").

8. Enclosed as Exhibit E are true and accurate copies of a Provisional Application for Patent Cover Sheet and an enabling disclosure of the invention as claimed (the "First Provisional Application"). Upon my best knowledge and belief, the first provisional application was filed by Attorney Matthew E. Connors on January 5, 2001 and was assigned Attorney Docket Number BU.5901. In pertinent part, the First Provisional Application includes the wearable and portable, microprocessor-based embodiment of the device in Figure 1 on page 5 of Exhibit A.

9. Enclosed as Exhibit F is a true and accurate copy of an Official Filing Receipt from the United States Patent and Trademark Office for the First Provisional Application. Upon my best knowledge and belief, the First Provisional Application received application number 60/260,134 and an official filing date of January 5, 2001.

To the issue of due diligence, efforts to actually reduce to practice a portable, microprocessor-based prototype of the invention as claimed included:

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10. Upon my best knowledge and belief, the experimental testing was performed in March and April 2000. Enclosed as Exhibit G are true and accurate copies of meeting notes of the Injury Analysis and Prevention Lab Staff dated March 15, 2000, April 19, 2000, and May 17, 2000 showing due diligence. The meeting notes of March 15th provide that Mats "is making some exciting progress on his foot pressure device project." The meeting notes of April 19th provide that Peter "has designed a model to help understand stabilogram diffusion parameters"; that the "device [Mats] built has been in constant use everyday since he left [to return to Sweden]"; and that Nick "is using the pressure device built by Mats to see if normal subjects can improve their balance with increased feedback provided as vibration." The meeting notes of May 17th provide that "Nick finished and did GREAT. Very impressed with their efforts . . ."

11. Enclosed as Exhibit H are true and accurate copies of laboratory notebook pages 127-129, which upon my best knowledge and belief were prepared on or about July 2, 2000, showing continued due diligence. More specifically, in pertinent part, page 127 shows some calculations for scaling the center of pressure (COP) to the subject; page 128 discusses preliminary analysis of RMS sway experimentation; and page 129 shows summary

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tables of data for stabilogram-diffusion (SD) analysis of falling subjects ("fallers") and non-falling subjects ("non-fallers").

12. Enclosed as Exhibit I is a true and accurate copy of the dissertation prospectus of Peter Meyer ("Meyer"), which upon my best knowledge and belief is dated December 12, 2000, showing continued due diligence and future work "to test hypotheses regarding the role of plantar cutaneous afferents in normal balance control" at page 10.

13. Enclosed as Exhibit J are true and accurate copies of testing protocol tables for Meyer's experimentation, which upon my best knowledge and belief is dated December 14, 2000, showing continued due diligence.

14. Enclosed as Exhibit K are true and accurate copies of laboratory notebook pages 89-90, which upon my best knowledge and belief were prepared on or about January 10, 2001, showing continued due diligence. More specifically, page 89 shows summaries of data for ten (10) subjects wearing the device.

15. Enclosed as Exhibit L is a true and accurate copy of Meyer's progress report to the National Aeronautics and Space Administration ("NASA), which upon my best knowledge and belief was prepared on or about January 23, 2001, showing continued due diligence and providing a schedule for future work. More

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specifically, Exhibit L provides that "[q]uiet stance data has [sic: have] been collected and analyzed for seven subjects under normal, reduced, and enhanced plantar sensation conditions. Subjects were tested with and without vision as well as in bipedal and unipedal stance. In addition, ten healthy subjects were tested during quiet stance with and without the use of the prosthetic foot sole" at page 1. Moreover, future work will entail analyzing "balance parameters from three additional subjects . . . during quiet stance with normal, increased, and decreased plantar pressure sensation [and analyzing] [a]utomatic postural responses to support surface translations . . . in ten healthy subjects with temporary anesthesia of the foot soles" at page 1.

16. Enclosed as Exhibit M is a true and accurate copy of a July 9, 2001 letter to Mr. Eilert Klatte, offering him a Visiting Research Assistant position at Boston University to transform the March 24, 2000 prototype "into a portable one suitable for use in field-testing."

17. Enclosed as Exhibit N is a true and accurate copy of a description for an internship project given to Mr. Eilert Klatte by Professor and co-inventor Lars Oddsson. The project description file is dated July 20, 2001. Upon my best knowledge

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and belief the internship project description was given to Mr. Eilert Klatte on or about July 20, 2001.

18. Mr. Eilert Klatte worked on hardware and software implementation of the second, wearable and portable, microprocessor-based prototype during the Fall 2001 - Winter 2002 term at Boston University, which is to say between September 2001 and February 2002. A true and accurate copy of a summary of Mr. Klatte's cumulative design and testing work is provided as Exhibit O, which is entitled "Design of a Mobile Artificial Sensory System for Feet, Internship Project September 2001 - February 2002."

More specifically, with respect to and quoting from independent claim 71, "a system for assisting the maintenance of balance over time during standing and gait of a user" is disclosed in the "Goals and Objectives" section on page 4 (i.e., "The goals of the proposed project are to design and build a mobile device that may substitute sensory information from the feet during gait."); "a sensing layer adapted for user wearing under a user's foot during conditions of standing and gait, said layer having a plurality of sensors positioned for sensing two dimensional force distribution under said user's foot" is shown in Figure 1 on page 5 and further disclosed in the "Abstract" on page 2 (i.e., "Feet sensors with electronic, stimulus feedback and a real time

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controlling of the parts together are the three major parts of this project."); "excitation means for said sensors which, during user standing and gait, provide signals representing user balance information as a function of said two dimensional force distribution over time" is shown in three levels in Figure 1 on page 5 and is further disclosed in the "Hardware Design" section on page 5 ("Each vibrator can be single addressed through the microcontroller and there are 16 steps of intensity through the D/A conversion possible."); "said sensing layer adapted to transmit said balance information signals to a remote location under conditions of standing and gait" is disclosed on page 4 in the "Introduction" section (i.e., "Eight analog inputs are directly supported on the microcontroller, so that the 7 FSR's can be connected without any further A/D."); "a signal processing subsystem at said remote location and adapted to be user wearable, said subsystem configured to receive said balance information signals and to provide in response thereto balance control signals containing temporal and spatial information reflecting said force distribution for use in user skin stimulation" is shown in Figure 1 on page 5 and is further disclosed in the "Hardware" section on page 5 (i.e., "Eight analog inputs are directly supported on the microcontroller, so that the 7 FSR's can be connected without any

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further A/D."); "an array of a plurality of stimulators adapted for attachment in contact with a skin area of said user" is shown in Figure 1 on page 5 and is further disclosed in; and "said plurality of stimulators arranged in a two dimensional array and responsive to said balance control signals to provide skin stimulation to said user in a form reflecting said two dimensional force distribution under said user's foot both spatially and temporally in said two dimensional force distribution over time, both under conditions of standing and gait, to thereby provide feedback to the user via the array of plural stimulators to provide individualized spatial mapping and temporal information to allow complex, multi-dimensional and time varying corrective action" is shown in Figure 1 on page 5 and is further disclosed in the "Goals and Objectives" section on page 4 (i.e., "Data acquisition and signal processing should be achieved to provide a proper feedback. This includes both real-time feedback, collecting pressure information from the feet and at a certain time with a proper computation make a feedback to the body.").

With respect to and quoting from independent claim 72, a "system for assisting the maintenance of balance over time during standing and gait of a user" is disclosed in the "Goals and Objectives" section on page 4 (i.e., "The goals of the proposed

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project are to design and build a mobile device that may substitute sensory information from the feet during gait."; "a sensing layer adapted for user wearing under a user's foot during conditions of standing and gait, said layer having a plurality of sensors positioned for sensing two dimensional force distribution under said user's foot" is shown in Figure 1 on page 5 and further disclosed in the "Abstract" on page 2 (i.e., "Feet sensors with electronic, stimulus feedback and a real time controlling of the parts together are the three major parts of this project."); "excitation means for said sensors which, during user standing and gait, provide signals representing user balance information as a function of said two dimensional force distribution over time" is shown in three levels in Figure 1 on page 5 and is further disclosed in the "Hardware Design" section on page 5 ("Each vibrator can be single addressed through the microcontroller and there are 16 steps of intensity through the D/A conversion possible."); "said sensing layer adapted to transmit said balance information signals to a remote location under conditions of standing and gait" is disclosed on page 4 in the "Introduction" section (i.e., "Eight analog inputs are directly supported on the microcontroller, so that the 7 FSR's can be connected without any further A/D."); "a signal processing subsystem at said remote

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location and adapted to be user wearable, said subsystem configured to receive said balance information signals and to provide in response thereto balance control signals containing temporal and spatial information reflecting said force distribution for use in user skin stimulation" ; "an array of a plurality of stimulators adapted for attachment in contact with a skin area of said user" is shown in Figure 1 on page 5; "said stimulators arranged in plural vertically separated horizontal rows" is shown in Figure 1 on page 5; and "said plurality of stimulators responsive to said balance control signals to provide skin stimulation to said user in a form reflecting said two dimensional force distribution under said user's foot both spatially and temporally in said balance control signals to provide skin stimulation to said user reflecting said two dimensional force distribution changes over time both under conditions of standing and gait, to thereby provide feedback to the user via the array of plural stimulators to provide individualized spatial mapping and temporal information to allow complex, multi-dimensional and time varying corrective action" is shown in Figure 1 on page 5 and is further disclosed in the "Goals and Objectives" section on page 4 (i.e., "Data acquisition and signal processing should be achieved to provide a proper feedback.

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This includes both real-time feedback, collecting pressure information from the feet and at a certain time with a proper computation make a feedback to the body.").

19. Enclosed as Exhibit P are copies of staff meeting notes of the Injury Analysis and Prevention Lab Staff designated IP43-IP48 corresponding, respectively, to monthly staff meetings of September 19, 2001, October 17, 2001, November 21, 2001, December 19, 2001, January 16, 2002, and February 20, 2002. The minutes show continuous progress in the September 2001 through February 2002 timeframe summarized in monthly progress reports in developing the invention as claimed.

20. Enclosed as Exhibit Q is a copy of programming code for the foot pressure device dated February 11, 2002, which is mentioned in the IP47 staff meeting notes of January 16, 2002 of Exhibit J.

21. In summary, a March 24, 2000 actual reduction to practice of a PC-based embodiment of the invention as claimed preceded the publication date of the priority document relied on by Haugland, which is to say August 23, 2001. In addition to an actual reduction to practice, a constructive reduction to practice of the PC-based and a microprocessor-based embodiments of the invention as claimed, i.e., the First Provisional Application, preceded the publication date of the priority document relied on by Haugland.

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22. In addition to an actual reduction to practice and a constructive reduction to practice of a PC-based embodiment of the device of the invention as claimed prior to the publication date of the Haugland priority document, due diligence (as described hereinabove) was used to transform the May 11, 2000 constructive reduction to practice of the microprocessor-based embodiment of the invention as claimed.

23. Having been duly warned that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the U.S. Code and may jeopardize the validity of the application and any patent issuing thereon, I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true.

Peter F. Meyer
Peter F. Meyer

4/23/10
Dated

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Exhibit A

Application to
The Provost's Innovation Fund 2001

BOSTON UNIVERSITY

A Wearable Foot Pressure Sensory Substitution Device for Individuals with Peripheral Neuropathies

Inventors:

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c. Feb 15, 2001

a. The Problem to be Addressed

An estimated 4.8 to 6.4 million Americans exhibit symptomatic diabetic peripheral neuropathy (DPN), comprising 30-40% of the U.S. diabetic population [1, 14, 26]. The prevalence of DPN may be as high as 50% in diabetics over 60 years of age. When added to an estimated 10% of the non-diabetic elderly population suffering from peripheral neuropathies [14], up to 20% of the elderly population may be affected by peripheral neuropathies [32]. These individuals gradually lose sensation of foot pressure, which normally provides important information to the balance control system. It has been shown that these patients exhibit decreased stability while standing [13] as well as when they are exposed to perturbations of their balance [18]. Furthermore, epidemiological evidence has linked peripheral neuropathies to an increased risk of falling [34, 35]. Acute injuries occurring as a result of falls, including traumatic brain and spinal cord injuries, are a common source of impairment, disability and even death. According to the CDC, falls are the leading cause of accidental death in the elderly population. Overall, balance disability is a serious public health problem associated with human suffering and extremely high costs to society. There is evidence that the balance deficits seen in peripheral neuropathy patients may be related to their reduced ability to sense pressure fluctuations under the feet. Altered foot pressure sensation may also contribute to the balance and gait deficits reported by astronauts returning from microgravity exposure. In contrast to patients with DPN, however, astronauts exhibit hypersensitivity of the foot soles.

In this application we present a plan to build a sensory substitution device to be worn by individuals with balance problems related to altered foot pressure sensation. A lab-based functioning prototype has already been built. The device measures foot pressure and extracts balance related information which is provided to the individual as a vibrotactile cue that can be used to maintain upright balance. Our preliminary research suggests that such a device can significantly improve the postural stability of patients suffering from reduced foot sole pressure sensation. In addition, this device may lead to the development of in-flight countermeasures as well as post-flight rehabilitation techniques to maintain and/or restore normal foot sole sensation in astronauts during and after space flight. A provisional patent for this device has been filed through the Boston University Office of Technology Transfer (BU00-67). In the current application we propose to build a second generation version of this device and to perform further testing of the device outside of the lab environment.

b. Importance of the project

b.1. Control of Posture

The human balance control system incorporates a large number of muscles and joints, creating a statically indeterminate system with many degrees of freedom. The task of the postural control system is to maintain the center-of-mass (COM) over the base of support, which is formed by the feet in the standing position. Impaired standing balance occurs when either the position of the COM with respect to the base of support is inaccurately sensed or the automatic movements required to bring the COM into a balanced position are untimely or poorly coordinated [30]. Maintenance of COM position during upright stance is generally accomplished through activation of muscles that produce torque around the ankle [15, 28]. Amplitude and timing of the these postural corrections are modulated by feedback from three sensory systems: the vestibular, visual, and somatosensory systems. The vestibular system encodes linear (including gravitational) and angular accelerations of the head with respect to inertial space. Vision measures the orientation of the eyes with respect to the surround. The somatosensory system includes a number of sensory sub-systems that provide information regarding the orientation of body segments with respect to each other and the external environment. At least four of these sub-systems are involved in the control of standing balance. Golgi tendon organs encode muscle force, while muscle spindles are sensitive to both muscle length and velocity of stretch. Joint mechanoreceptors provide information regarding contact forces occurring within joints and cutaneous mechanoreceptors encode pressure and skin stretch under the soles of the feet, thus providing feedback regarding the distribution of body load onto the support surface.

b.2. The Role of Plantar Cutaneous Afferents in Control of Posture

Among the various somatosensory systems involved in balance control, plantar cutaneous sensation is of particular interest for a number of reasons. A simple inverted pendulum model for quiet stance predicts that the position of body COM could be internally computed by the central nervous system (CNS) as a simple function of normal force gradient and shear force under the foot soles [29]. Furthermore, plantar cutaneous sensation is the most obvious and earliest sensation lost as a result of diabetic peripheral neuropathy (DPN) [11] and the loss of plantar pressure sensation is well correlated with balance deficits associated with DPN [38]. The most common form of DPN is a distal symmetric sensory neuropathy [26], which begins with a loss of sensation in the fingers and toes and spreads proximally as the condition progresses [4]. Studies have documented increased thresholds for the perception of cutaneous pressure stimuli in DPN patients [3, 14, 16, 38]. Microneurographic recordings from individual cutaneous mechanoreceptors in DPN patients show a decreased ability to transmit sustained action potential trains in response to sustained pressure [23]. In addition to the large percentage of diabetics, peripheral neuropathies affect approximately one third of AIDS patients [27, 39]. Other conditions that may result in peripheral sensory neuropathies include Gullian-Barre syndrome, Charcot-Marie-Tooth disease, and lead poisoning.

Given the importance of somatosensory feedback in posture control, it is not surprising that patients suffering from sensory neuropathies demonstrate balance deficits. Peripheral neuropathies have been strongly linked to the risk of fall-related injuries [2, 32, 35] as well as a reduced perception of safety in unfamiliar physical surroundings [2]. DPN patients exhibit greater sway during quiet stance than matched control subjects, suggesting a greater degree of postural instability [2, 4, 37, 38]. Richardson and colleagues found that moderate peripheral neuropathy in elderly subjects was associated with a dramatic reduction in their ability to maintain a unipedal stance [33], indicating a potential gait instability.

The technology described in this proposal is an offshoot of an ongoing research study being conducted by the applicants at the NeuroMuscular Research Center. This study, supported in part by NASA, involves an investigation of the specific role played by the foot pressures sensors in the control of posture. For this purpose, we have developed a unique technique based on iontophoretic application of cutaneous anesthesia. Previous studies have investigated the role of the foot pressure sensation by temporary removal of afferent sensation from the feet through ischemic [10, 17] or hypothermic anesthesia of the foot [24, 25]. However, in addition to the cutaneous afferents of the foot sole, these techniques will also affect muscle spindle, Golgi tendon organ, joint mechanoreceptor afferents and muscle efferents within the foot. Our technique specifically targets the cutaneous mechanoreceptors of the foot sole, eliminating confounding effects on other afferent and efferent systems. Preliminary results derived from this work strongly support the hypothesis that pressure sensors within the skin of the foot soles play an important part in the maintenance of standing balance. Furthermore, our results suggest that balance deficits seen in DPN patients and in astronauts may be directly related to alterations in foot sole sensitivity.

b.3. Data analysis

We analyze quiet stance with the stabilogram-diffusion method [6-8, 21, 36]. Derived from statistical mechanics, this method involves the modeling of COP displacements during quiet stance as a quasi-random walk. Briefly, fractional (or fractal) Brownian motion is described by the equation

$$\langle \Delta r^2 \rangle \sim \Delta t^{2H}, \qquad (1)$$

where Δt is a time interval, $\langle \Delta r^2 \rangle$ the mean-squared displacement occurring over Δt, and H is the scaling exponent. The autocorrelation coefficent in this case is given by $C = 2(2^{2H-1}-1)$. A scaling exponent $H>0.5$ signifies postively correlated behavior and is termed *persistence;* $H<0.5$ describes negatively correlated behavior or *antipersistence*. As H increases, low frequency noise within a time series increases and produces excursions (drift) which are large in amplitude with respect to the high frequency components. In contrast, low values of H correspond to very noisy data, where low frequency excursions are of the same order of magnitude as local higher frequency noise [12]. A scaling exponent of 0.5 produces an uncorrelated random walk and can be described by the equation

$$\langle \Delta r^2 \rangle = 2D\Delta t, \qquad (2)$$

where D is the diffusion coefficient. In order to describe stochastic activity in COP time series where $H \neq 0.5$, Collins & De Luca (1993) redefined D in equation (2) as the "effective diffusion" coefficient. The coefficients D and H are determined from the slopes of the linear and log-log plots of $<\Delta r^2>$ versus Δt, where r is the COP displacement in either the mediolateral or anteroposterior directions.

Stabilogram-diffusion analysis of COP trajectories reveals behavior over two different times scales that can be described by different diffusion and scaling coefficients. The transition between these two regions occurs at the *critical time*. This represents the time interval at which the stabilogram-diffusion curve first crosses from persistence to antipersistence (H = 0). This may be considered the average time interval at which the postural control system is able to arrest the persistent motion of the body.

b.4. Microgravity Adaptation and Balance Control

Upon return to terrestrial gravity, astronauts exhibit noticeable changes in their ability to maintain balance. During quiet stance, they demonstrate increased body sway amplitude [9, 31] and increased tremor [5, 20]. Astronauts' ability to compensate for external postural perturbations is also degraded [20, 31]. While the source of these postural deficits remains unclear, one of the afferent feedback systems which has been implicated is that of the plantar cutaneous mechanoreceptors. Under microgravity conditions, foot sole pressure receptors remain largely unloaded. The loss of foot pressure stimulation in microgravity appears to be directly related to a suppression of anticipatory postural adjustments associated with rapid arm movements [22]. After long-term microgravity exposure, plantar afferents may exhibit increased vibration sensitivity for 36 or more days post-flight [20]. Unfortunately, further elucidation of the role played by plantar sensitivity on post-flight balance control is confounded by concurrent changes in vestibular function [31], joint proprioception [5, 20], and motor function [19, 20]. Further understanding of the contribution of plantar afferents to post-flight postural instabilities may lead to the development of improved countermeasures to be used by astronauts. Such countermeasures might consist of repeated vibration or other mechanical stimulation of the foot soles during and/or after space flight in order to reduce the hypersensitivity developed in weightlessness.

c. Expected Tangible Results

In the following section we will briefly describe our previously achieved results, which will provide the basis for the current proposal, and also present what we expect to accomplish during the proposed project. A provisional U.S. patent was filed for this device in January of 2001 and the rights assigned to Boston University. A utility patent must be filed within one year of the filing provisional patent. Our responsibility in the meantime is to help B.U.'s Office of Technology Transfer identify potential licensees of this technology. The proposed project will be a major step in verifying the potential of this device to improve postural stability in a large population of patients in need. Demonstrated success of the device on patients after extended use will dramatically increase the attractiveness of this technology to potential licensees. This project is therefore expected to directly benefit Boston University as well as the public at large.

c.1. Importance of foot pressure for balance control

Mr. Meyer's doctoral dissertation research, supervised by Prof. Oddsson, involves a study of the role played by foot sole pressure sensors in normal balance control. Using a novel anesthetic technique that specifically targets the cutaneous foot sole, we have demonstrated that a reduction in sensation from only small portions of the foot sole leads to a dramatic increase in postural sway. Based upon our statistical mechanics models and several methods of data analysis, we have interpreted these changes as a reduced ability to maintain a postural reference position, leading to increased low-frequency drift in the COP (increased long-term persistent activity). We hypothesize that patients suffering from reduced foot sole sensation will have even greater difficulties in maintaining their reference position, increasing their risk of falls. We have recently solicited funding from NIH to study postural control in patients suffering from the early stages of peripheral neuropathy.

c.2. Sensory substitution prototype

A first generation lab-based prototype of the sensory substitution device has been built. A picture of the peripheral components of the prototype are shown in Figure 1. In brief, the device consists of a series of

pressure sensors that are placed at specific locations under the feet. The pressure signals are acquired by a PC with a special A/D card with an on-board microprocessor programmed to perform a series of calculations on the pressure signals. The results of these calculations are used to drive 16 digital outputs on the A/D card that in turn activate eight small vibrators placed around the lower legs of the subject (shown in Figure 1). The subject is instructed to use the vibrations as an indicator of upright body position. When the subject is standing upright, the vibrations will decrease. Increased sway in a certain direction will increase the vibration on the same side of the leg as the direction of the sway. Thus. the subject can learn to decrease the amount of body sway by maintaining a position where the vibrations are minimal.

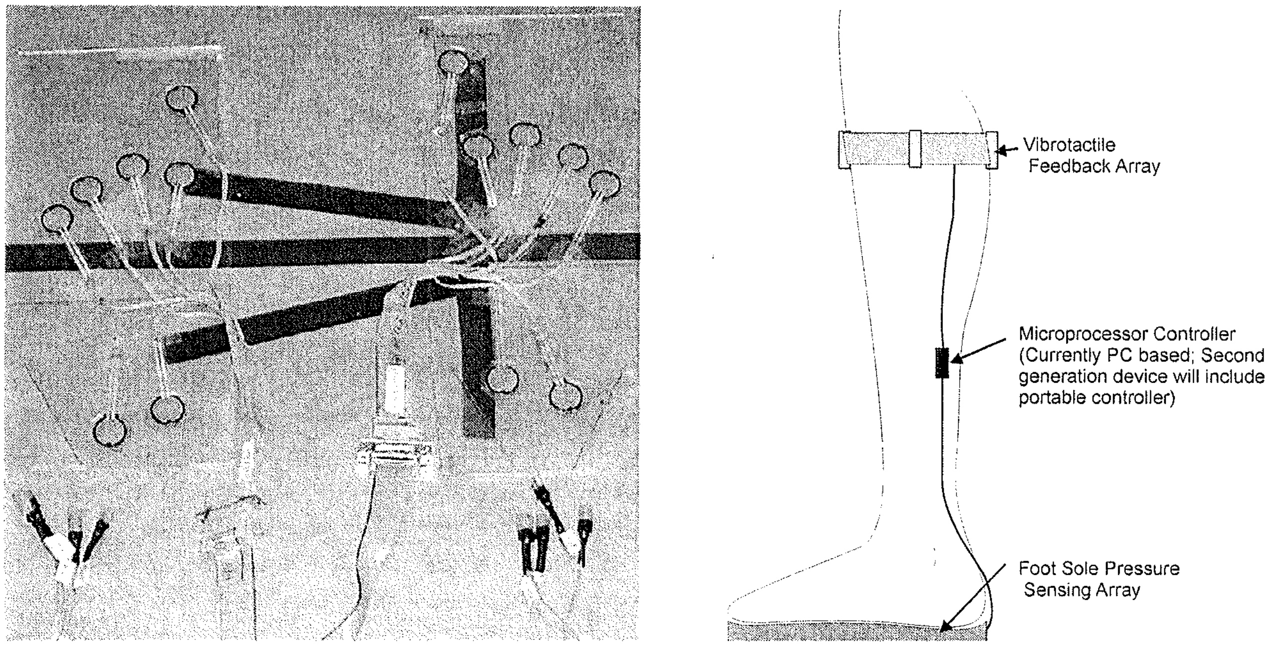

Figure 1. *First prototype of sensory substitution device (left) and a drawing showing how a fully portable device would be worn by a subject (right). The peripheral components including seven pressure sensors for each foot (top left) as well as four vibrators that can be placed around each leg are shown (lower left).*

c.3. *Results from tests with the sensory substitution prototype device on healthy subjects.*

A group of ten healthy subjects were instructed to stand as still as possible with their eyes closed under two different conditions - with or without vibrotactile feedback. The amount of body sway was measured with a tri-axial force platform upon which the subjects were standing. Ten trials of 30s duration were performed during bipedal stance with and without vibrotactile feedback with the eyes closed. Subjects were instructed to stand as still as possible and to avoid positions that generated vibrations from the device.

All subjects were able to sway less when they were guided by the vibrotactile feedback information. The most notable effect of providing vibrotactile feedback during bipedal stance was a 70% highly significant reduction ($p < 0.005$) in the long-term anteroposterior scaling exponent, reflecting the long-term drift in the body sway while standing. Interestingly, this effect is opposite to what we see in subjects during foot sole anesthesia, suggesting that the vibrotactile device can be used to cancel the effect of lost foot pressure sensation on postural control.

c.4. *Expected future results.*

Functional testing of the current prototype has been limited by the bulk of the computer and custom electronics used to control the system. We expect that patients suffering from peripheral neuropathies may require extended training with the device before it becomes truly useful and functionally transparent as a balance aid. Such long-term training with the device will likely require several days of steady use and cannot be practically performed with the current prototype. We therefore propose to design and build a second generation portable prototype that can be worn by test subjects for an extended period of time before quantitative balance assessment. This would represent an important step towards the development of a fully

ID	Task	Duration	Months											
1	Analysis of previous design	1 mo												
2	Re-design	2 mo												
3	Prototyping and Lab Testing	2 mo												
4	Evaluation and Re-design	2 mo												
5	Lab Testing	2 mo												
6	Final Implementation	2 mo												
7	Field Testing	4 mo												
8	Evaluation	4 mo												

Table 1. *Suggested timetable for the development of second generation prototype of a sensory substitution device.*

wearable and self contained sensory substitution device that can be used by individuals with peripheral neuropathies on a daily basis.

d. Work Plan

d.1. Tentative Time Table:

A timetable for the current project is given in Table 1 below.

The first six months of the project will be focused on the redesign and building of the new device. The development of a portable prototype is a considerable challenge, since the device must be small, lightweight, and remain powered by a battery for an extended period of time. In order to accomplish this task, we propose to offer the design and prototyping phase of the project as a Masters thesis project for two engineering mechatronics student from the Royal Institute of Technology in Stockholm, Sweden. Over the past 6 years Dr. Oddsson has maintained a graduate student exchange program with the Department of Mechatronics at the Royal Institute of Technology in Stockholm, Sweden. Students of Dr. Mats Hanson at the Department of Mechatronics spend 6 months at the NeuroMuscular Research Center working on a mechatronics design project that incorporates a biomedical component. For example, the current prototype of the sensory substitution device was built by one of these students last year. These students write a Masters Thesis that they defend at the Royal Institute of technology in Stockholm. Over the past six years, 17 students have participated in this successful exchange program. There are currently two students from this program working on an unrelated project at the NeuroMuscular Research Center.

The final six months of this project will involve field testing of the second generation device. A small number of healthy volunteers will be recruited to wear the device for several days in order to assess the robustness and reliability of the design. The final stage will involve preliminary testing with patients suffering from the early stages of DPN, recruited through our contacts with faculty at the Boston University School of Medicine.

d.2. Conclusion

Numerous studies have established a link between reduced sensation in the foot and ankle and measurable balance deficits. Our ongoing research indicates that these deficits may be due in large part to the loss of sensation from the skin of the foot soles. There exists a large population of patients suffering from reduced plantar sensation, and the costs associated with falls and fall-related injuries are enormous. It is therefore critical that we develop assistive technology or other means to reduce the risk of falls in these patients and improve their quality of life. Testing of the prototype prosthetic foot sole has indicated that our technology may be effective in substituting an alternative stimulus for foot sole pressure that can be readily integrated into the postural control system. The next logical step is the development of a second-generation, portable version of this device that will allow more extensive testing of the concept under real-life conditions.

e. Budget

Personnel	
Stipends for 2 Mechatronics Grad Students	10,000
Stipend for Post-Doc, Peter Meyer	7,000
Personnel total	**17,000**
Equipment	
Dedicated PC & A/D card	4,000
Embedded controller setup	3,000
Electronics Material	1,000
Equipment total	**8,000**

Total Cost $25,000

e.1. Budget justification

Mechatronics Graduate Students:
Two students will be recruited from the Department of Mechatronics at the Royal Institute of Technology in Stockholm, Sweden for the project. These students are highly skilled in this field and they have the expertise required for the current project. They will be supervised locally by Dr. Oddsson and Mr. Meyer as well as by Dr. Hanson in Sweden. They will be responsible for redesign and building of the portable prototype. They will be involved in the first 6 months of the project. Each student will be paid a stipend of $5,000 to cover living expenses during their stay in Boston.

Post Doctoral Fellow, Peter Meyer
Mr. Meyer will perform the field testing and the evaluation of the prototype device. Mr. Meyer is currently working on his dissertation *"The role of plantar cutaneous afferents in static and dynamic balance control"*, which has provided some of the background work for the current proposal. He will defend his dissertation in September of 2001. This stipend will allow Mr. Meyer to maintain involvement with the project in his transition to post-doctoral work.

Equipment
A Dedicated PC & A/D Card as well as the embedded controller setup is required for the development of the portable prototype. Electronics material consist of parts and electronics for the actual device.

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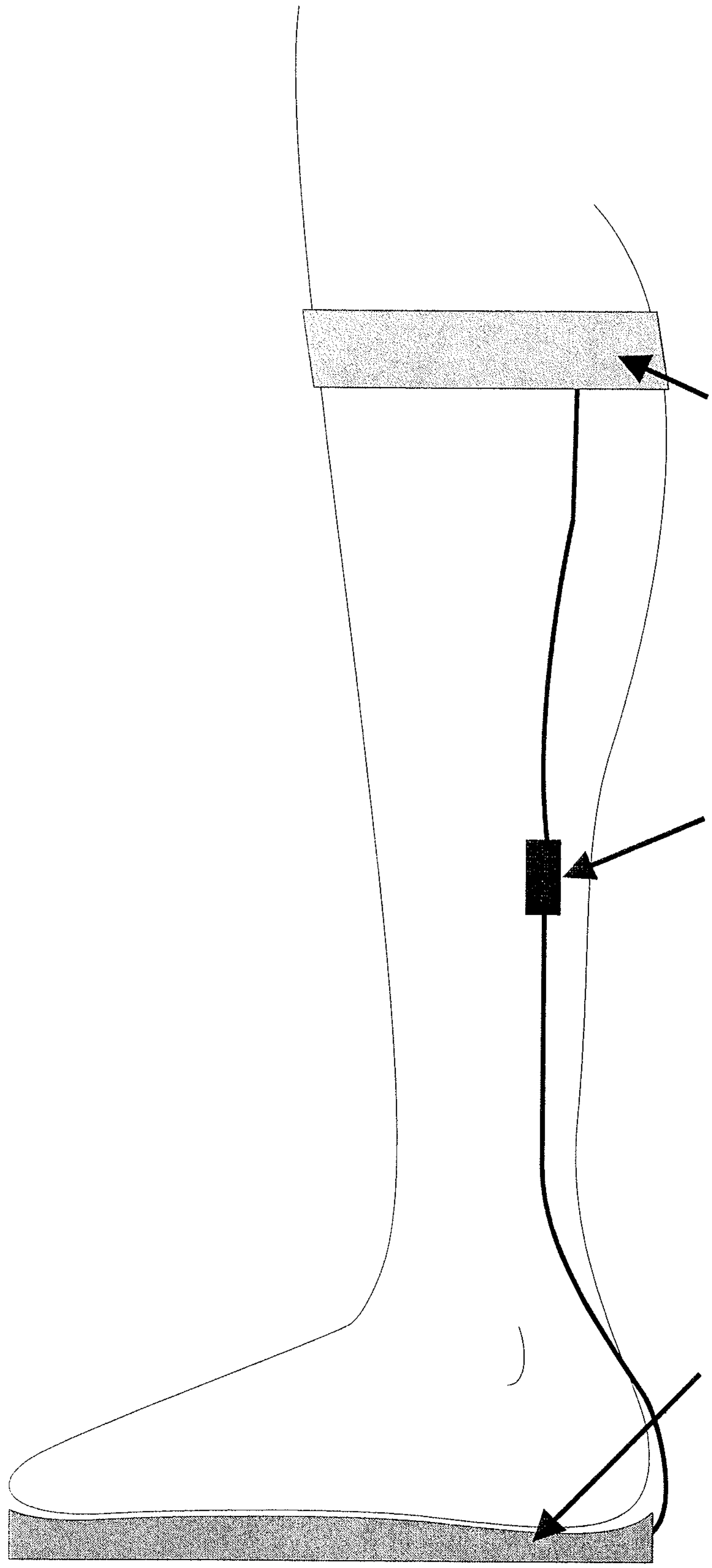
Inventors: Peter Meyer & Lars Oddsson

Preferred Embodiment Shown Exhibit B

Uses: Improving static and dynamic balance control, especially in patients suffering from reduced plantar pressure sensation; simulation of balance conditions (Virtual Reality); stimulation of plantar pressure receptors to reduce adverse adaptations to reduced weight bearing (i.e. prolonged bedrest or microgravity exposure).



1) Feedback Array:
Vibrotactile or electrotactile cutaneous feedback encodes position of foot Center-Of-Pressure and/or weight distribution by modulating one or more of the following: stimulus frequency, stimulus amplitude, location of stimulus or number of active stimulators. This Element(s) is located adjacent to the skin of the leg or thigh. The location of active stimulator(s) on the skin in the transverse plane will directly reflect the location of the foot Center-of-Pressure in the transverse plane.

2) Signal Processor/Controller:
Converts electrical or mechanical signal(s) from Plantar Pressure Sensor Array into signal(s) which control the activity of the Feedback Array element(s). May be implemented as a discrete system component or be imbedded within the Plantar Pressure Sensor Array or Feedback Array. Performs an estimation of the position of the Center-of-Pressure under the foot and/or the fraction of body weight supported by the foot. These estimates are then used to produce an appropriate output signal to the Feedback Array. A "dead-zone" may be implemented such that Center-of-Pressure position within a certain range and/or foot load below a certain threshold may produce no output to the feedback elements.

3) Plantar Pressure Sensor Array: Transduces pressure distribution under the foot and transfers that information to the Signal Processor/Controller.

Bipedal Device; only one leg shown. One or more of modules may be held against the skin in a stocking. Sensor array module may be incorporated into a shoe or implemented as a shoe insert. Connection between modules may be wireless. Feedback elements may be incorporated into a a shoe or shoe insert.

5/11/2000

INTRODUCTION

Pressure sensation from the soles of the feet provides important information to the human postural control system [1,2]. In patients over the age of 60, diabetes mellitus often results in peripheral neuropathies that impair this sensation by degrading the peripheral sensory system. These patients may exhibit postural control deficiencies and an increased risk of falling [2,3]. The objective of this project was to investigate the potential of a prototype foot-sole pressure sensory substitution system to increase postural stability in healthy subjects without postural deficiencies. This study is the preliminary investigation of the potential for a sensory substitution system to serve as a postural aid for patients suffering from peripheral neuropathy.

The sensory substitution device tested in this study was able to significantly alter the postural behavior of healthy subjects during quiet stance. These changes in postural behavior were quantified through the statistical analysis of parameters extracted from a series of ten 30 second trials of quiet standing under various conditions.

In conclusion, the sensory substitution system was able to elicit postural responses in healthy subject.

Further research is required to determine whether these postural responses would be beneficial to patients with impaired postural control systems.

BACKGROUND

Postural Behavior During Quiet Standing

The center of pressure (COP) is defined as the location of the resultant ground reaction force. When a person attempts to stand still, his or her COP will vary with time. The degree to which the COP varies is dependent upon the posture control system of the individual. A plot of the time-varying coordinates of the COP is known as a stabilogram, and can be generated using the data collected from a force plate (Figure 1a,b). A number of parameters have been proposed to quantify the changes in COP trajectory associated with different experimental conditions or pathologies. Collins and DeLuca 1993 proposed the use of parameters based upon a random walk model of the COP trajectory. In order to study the dynamic characteristics of a stabilogram, they plotted the mean square COP relative displacement $<\Delta x^2>$ versus time interval Δt. This plot is known as a stabilogram diffusion plot, and generates repeatable, physiologically meaningful parameters describing the posture control system of the subject (Figure 1c) [8]. A typical stabilogram diffusion plot has two distinct linear regions. The slope of each linear region is equal to two times the diffusion coefficient D for that region:

$$\frac{\langle \Delta x^2 \rangle}{\Delta t} = 2D$$

where the diffusion coefficient signifies the level of stochastic activity. The slope of the short-term linear region is

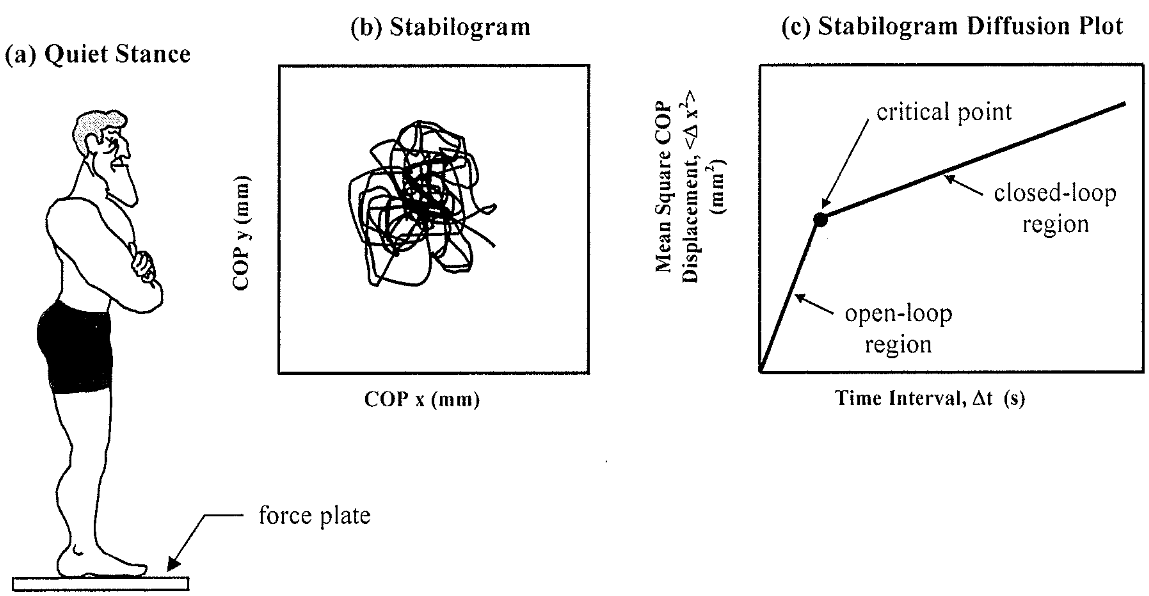


Figure 1: Cartoon showing analysis of posture control during quiet stance (a) cartoon of a subject in quiet stance, (b) a representation of a typical stabilogram, which shows the location of the COP of the subject over time, (c) a schematic representation of a typical stabilogram diffusion plot, which shows the dynamic characteristics of a stabilogram

generally greater than the slope of the long-term linear region, which indicates that the short-term region has a higher degree of stochastic activity. For this reason, it has been hypothesized that the short-term linear region is characteristic of open-loop posture control, while the long-term linear region is characteristic of closed-loop posture control [8]. The boundary between the short- and long-term regions is known as the critical point. Analysis of the parameters generated by a stabilogram diffusion plot (i.e. critical point and diffusion coefficients) has been demonstrated to be an effective method for quantifying posture control during quiet stance [8].

Postural Behavior Following a Simulated Slip

At Boston University's NeuroMuscular Research Center, slipping conditions are simulated exposing the subject to an un-cued surface perturbations on a programmable displacement platform called BALDER (BALance DisturbER) (Figure 2). In this case, it is the floor that slips from under the subject and causes a temporary loss of balance. Following the perturbation, the posture control system of the subject attempts to restore balance as quickly as possible. In order to quantify the postural behavior that occurs following a perturbation, surface electromyographic (EMG) signals are collected from the skin overlying the muscles that are used to restore balance. The magnitude of an EMG signal is the summation of individual motor unit action potentials trains, which are generated by discharges of active motor units in the muscle [9]. An EMG signal indicates the level of activity of the muscle from which it was recorded. In the case of small anteroposterior surface perturbations, the Tibialis anterior (TA) and Gastronemius lateral (GL) muscles of the leg will be used to restore postural stability (Figure 3). The onset time of EMG activation following a perturbation is a physiological parameters that can be used to characterize the postural response of the subject to a perturbation.

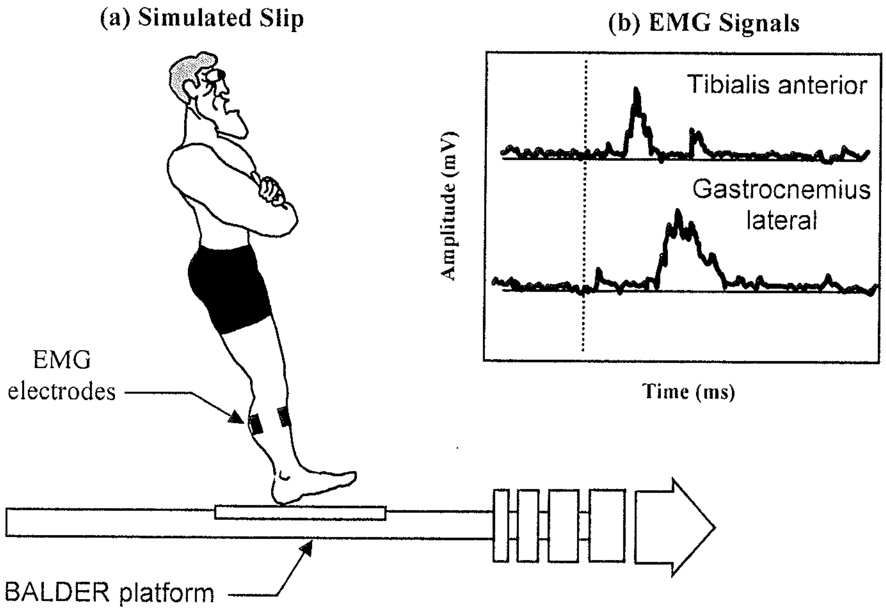


Figure 2: Cartoon showing analysis of posture control during a simulated slip (a) cartoon of a subject being perturbed in the anterior direction by the BALDER platform, (b) representation of typical EMG signals recorded from the Tibialis anterior and Gastrocnemius lateral muscles of the leg during a simulated slip, the broken line indicates the onset time of perturbation

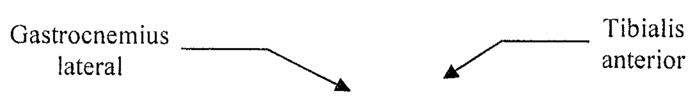


Figure 3: Anatomical view of muscles of right leg from lateral side, showing locations of the Gastrocnemius lateral and Tibialis anterior, the muscles of interest for collection of EMG signals during an anteroposterior perturbation

Physiology of Peripheral Neuropathy

The peripheral nervous system consists of sensory (afferent) and motor (efferent) nerves. Sensory nerves transmit information from the various receptors of the body to the central nervous system. Motor nerves carry signals from the central nervous system to the muscles and glands of the body. Peripheral neuropathy (PN) is a dysfunction of the peripheral sensory and motor nerves, and can be caused by diabetes mellitus [1]. In this form of PN, prolonged exposure to high blood glucose levels causes metabolic damage to the cell bodies of the peripheral nerves leaves the cell bodies increasingly unable to support their longest axons. Sensory nerves have cell bodies located close to the central nervous system, and very long axons that extend down to receptors in the limbs. This anatomical feature of the sensory nerves causes them to be first and most severely deteriorated by PN. This axonal dysfunction begins at the most distal region of the axon, and spreads in a gradient fashion toward the cell body. Over time, complete loss of function occurs. It is estimated that between 15% to 20% of the population over the age of 60 in the United States have varying degrees of PN [1].

Postural Instabilities Secondary to Peripheral Neuropathy

The somatosensory, vestibular, and vision systems are responsible for posture control in humans. The somatosensory system is considered by some researchers to be the most important of the three systems, and will be the focus of this project [1]. The somatosensory system receives sensory stimulus regarding body position and movement through three types of receptors: 1) joint mechanoreceptors, 2) muscle spindle fibers, and 3) cutaneous mechanoreceptors. Because PN causes the gradual deterioration of the nerves that innervate these receptors, it is not surprising to find that PN is related to postural instability.

Van den Bosch et al. 1995, studied the effects of PN on the threshold of ankle inversion and eversion, a quantitative indicator of postural stability. This threshold is the amount of ankle rotation required for a subject to accurately detect both the presence and direction of the rotation. Van den Bosch et al. showed that subjects with PN had an average ankle inversion/eversion threshold four times greater than the control group (Figure 4a) [3]. This lack of sensitivity in the ankle leads to an ambiguous sense of foot position, which may result in postural instability.

In another study, Richardson et al. 1996, investigated the effects of PN on unipedal quiet stance. They found that subjects with PN had difficulty reliably transferring weight from one foot to the other. Subjects with PN could only maintain a unipedal stance for approximately 10% of the average time attained by the control subjects (Figure 4b) [1]. This balance deficiency would be most detrimental to walking, when reliable transfer of weight from one foot to the other is critical.

Maximum duration of unipedal quiet stance and ankle rotation threshold are two measures of postural stability that reveal balance deficiencies caused by PN. These deficiencies are especially detrimental to elderly patients. Richardson et al. 1995, studied the correlation between elderly PN patients and their risk of falling [2]. The survey showed that 55% of the subjects with PN reported at least one serious fall in the prior year, as compared to only 10% of the age-matched control subjects (Figure 4c).

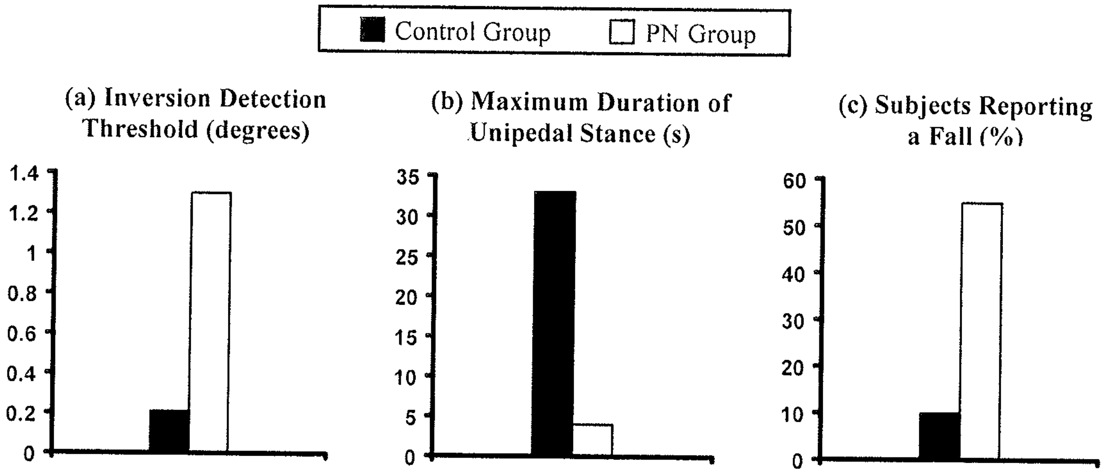


Figure 4: Graphs showing the postural instabilities induced by PN, (a) average inversion detection threshold for control subjects was 0.21°, for PN subjects it was 1.3°, (b) average maximum duration of unipedal stance for control subjects was 32.8 seconds, for PN subjects it was 3.8 seconds, (c) the percentage of subjects reporting having had a fall in the previous year was 10% for control subjects, for PN subjects it was 55%

While it is true that postural instability plagues a large percentage of the elderly population, sensory loss from the soles of the feet has not been isolated as the cause of this postural instability. Subjects with PN may have a host of lower extremity sensory, as well as motor dysfunctions. Horak et al. 1990, attempted to isolate the contribution of somatosensory information from the feet and ankles, of which foot-sole pressure is a component, to maintaining postural stability [4]. The subjects used in this study were healthy, middle-aged people, prior to and following anesthesia of the feet and ankles. Because somatosensory loss was induced in otherwise healthy subjects, the postural contributions of cutaneous and subcutaneous mechanoreceptors of the feet and ankles were isolated. Anesthesia was delivered by pneumatic pressure cuffs placed around the ankle joints to disrupt the blood flow below this point. This form of anesthesia has been argued to mimic the symptoms of PN [4]. EMG signals were recorded from several leg muscles during simulated slips on a moveable platform, prior to and following anesthesia. This study showed that somatosensory loss resulted in the selection of coordination patterns normally associated with large surface perturbations, but did not cause the responses to be delayed or disorganized [4]. Horak et al. concluded that the somatosensory information from the cutaneous and subcutaneous

mechanoreceptors of the feet and ankles is important in the selection of normal postural responses to a simulated slip. The other systems responsible for maintaining posture control, however, can compensate for this somatosensory loss in healthy subjects.

Sensory Substitution

For this project, foot-sole pressure was selected as the sensory information to be substituted in an attempt to elicit postural responses. Foot-sole pressure, however, is only one component of the total somatosensory information from the foot and ankle region. Muscle propioceptors, joint mechanoreceptors, and subcutaneous mechanoreceptors also provide somatosensory information from the foot and ankle region that may be important to normal postural behavior. The information provided by these receptors, however, is difficult to measure with a portable, non-invasive device. Foot sole pressure can be easily measured from outside the body, making it a convenient choice for somatosensory substitution.

Sensory substitution has previously been implemented in a number of diverse applications to restore sensory information to patients with disabilities. Phillips and Petrofsky 1986, developed a cognitive feedback system (CFS) that increased the postural stability of a paraplegic subject that could stand with the aid of functional electrical stimulation (FES) [6]. The CFS eliminated the subject's need for visual feedback of the position her legs. The pressure information from the soles of the subject's feet was measured by foot-load transducers, processed, and then relayed to vibrotactile stimulators mounted on the chest of the subject. This experiment demonstrated the improvement of balance using cognitive feedback of foot position. It remains unclear, however, whether such information can be successfully integrated into automatic postural responses.

METHODS

APPARATUS

The COP feedback system was used to estimate the location of the COP under each of the subject's feet in real time, and provide vibrotactile feedback the COP deviated from a predetermined threshold region. The flow chart for the COP feedback system is shown below (Figure 5). The system consisted of eight components:

- 2 Force Sensing Resistor (FSR) matrices (one for each foot)
- an FSR Amplifier Unit
- a Data Acquisition Processor (DAP) card
- a Personal Computer (PC)
- a Vibrator Amplifier Unit
- 2 vibrator arrays (one for each leg)

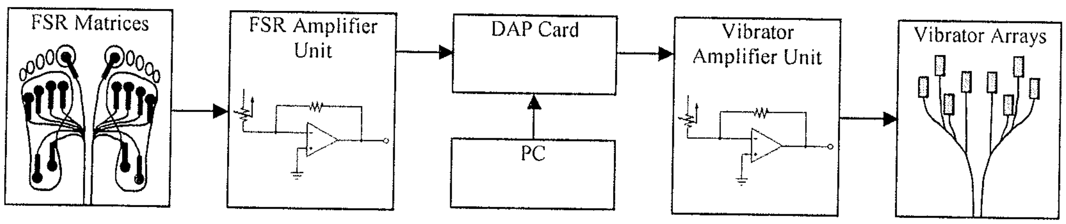


Figure 5 : Flow chart of the vibrotactile COP displacement feedback system

The COP is defined as the position of the resultant ground reaction force under the body. The location of this point can be estimated as the instantaneous average of the pressure distribution on the ground. This approximation of the location of the COP can be calculated from the outputs of force transducers arranged in a matrix to cover as much of the area of the pressure distribution as possible. The approximation becomes more accurate as the number of force transducers located within the pressure distribution increases.

A Force Sensing Resistor (FSR) is a force transducer that exhibits a decrease in resistance linearly related to the force applied to its active surface (Figure 6). Seven of these flat transducers were arranged in a matrix according to the locations of seven prominent bones in the subject's foot: the large toe, the 1st, 2nd, 3rd, and 4th metatarsal heads, the inferior medial navicular,

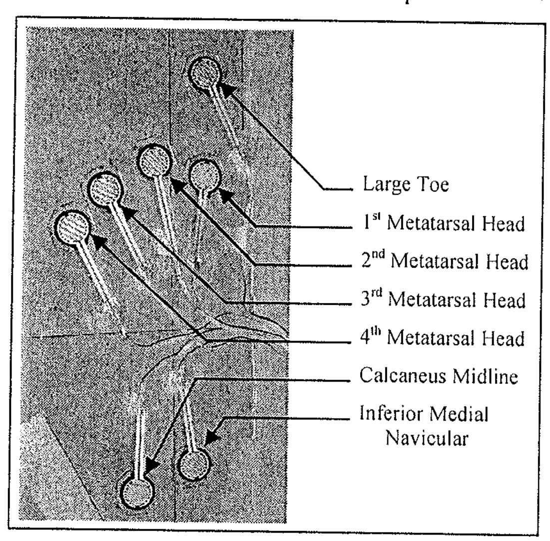


Figure 6: Diagram showing the locations of the Force Sensing Resistors (FSRs) in a left-foot FSR matrix. They are labeled according to their corresponding bone in the foot.

and the calcaneus midline (Figure 6). These bones were located on the subject's right foot, by inspection, and marked on the foot in ink. The subject's right foot was pressed down on a piece of paper to transfer the ink marks. The locations of the ink marks were then measured from an arbitrary coordinate axes system located on the paper. The locations of the FSRs relative to one another were required later for calculating an estimation of the location of the COP under each foot. The ink marks were then traced onto a transparency sheet, and used to position the FSRs on the transparency sheet. The FSR matrix for the left foot was constructed by mirroring the coordinates of the FSRs from the right foot because symmetry between the right and left foot was assumed.

The FSR Amplifier Unit incorporated each of the 14 FSRs (7 for each foot) into a separate current to voltage converter circuit (Figure 7). As the resistance of the FSR varied with the force applied to its active surface, the current through the FSR also varied. This current also flowed through the resistor Rg and generated a voltage signal (Vout) proportional to the force being applied to the FSR active surface. The FSR Amplifier Unit generated these force- controlled voltage signals for each FSR in the matrices. These output voltage signals were then sampled by the 14 analog input channels on the MicroStar Laboratories 2400 Data Acquisition Processor (DAP) card.

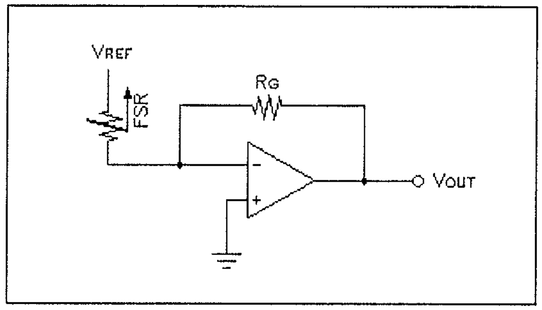


Figure 7: Schematic diagram of the current to voltage converter used to transform the force on the active surface of the FSR to a voltage output for recording

The data acquisition and processing of the DAP card was controlled by the software package DAP View. A Calibration program and a Feedback program were written in Visual C++ to make the necessary calculations for the feedback system. Using DAP View, these programs were downloaded from the PC onto the processor of the DAP card for real-time processing.

The location of the COP under each of the subject's feet was approximated as the average of the spatially weighted output values from the FSR Amplifier Unit. The average positions of the COP under each of the subject's feet were calculated over a 10 second period by the calibration program. These values were then entered into the feedback program and used as the reference positions for calculating the individual foot COP displacements during feedback. These estimated COP trajectories were then used to activate the vibrator arrays on the right and left legs.

Each vibrator array consisted of four vibrators associated with the anterior, posterior, medial, and lateral directions of the foot sole. The vibrators were circumferentially positioned around the subject's upper calves, facing in the directions to which they corresponded.

The inputs to each vibrator array were linearly related to the displacement of the subject's COP under the corresponding foot. This linear relationship was chosen such that the minimum vibrator

activation voltage (0.4V) corresponded to a predetermined COP displacement threshold, and the maximum vibrator activation voltage (2.5V) corresponded to a predetermined maximum COP displacement. The vibrator inputs were then sent to the Vibrator Amplifier Unit, which provided the current required to drive the vibrators. Once one of the COP displacements under the feet exceeded the threshold, the subject received vibration on the corresponding leg in the direction of the displacement. The intensity of the vibration was proportional the amplitude of the subject's COP displacement.

BALDER Platform System

The programmable, displacement platform BALDER provided the surface perturbations for the simulated slips experiment. The coordinate system on BALDER was such that the x- and y-axes formed the plane of the surface of the platform, and the z-axis pointed upward from the floor. The platform displacements were controlled by two AC servo-motors that moved the platform in the x- and y-directions. The position and acceleration of the platform in the plane of movement were measured by two linear potentiometers and two accelerometers. The forces and moments generated during the perturbation were measured by an Advanced Mechanical Technology (AMTI) force plate mounted in the center of the BALDER platform.

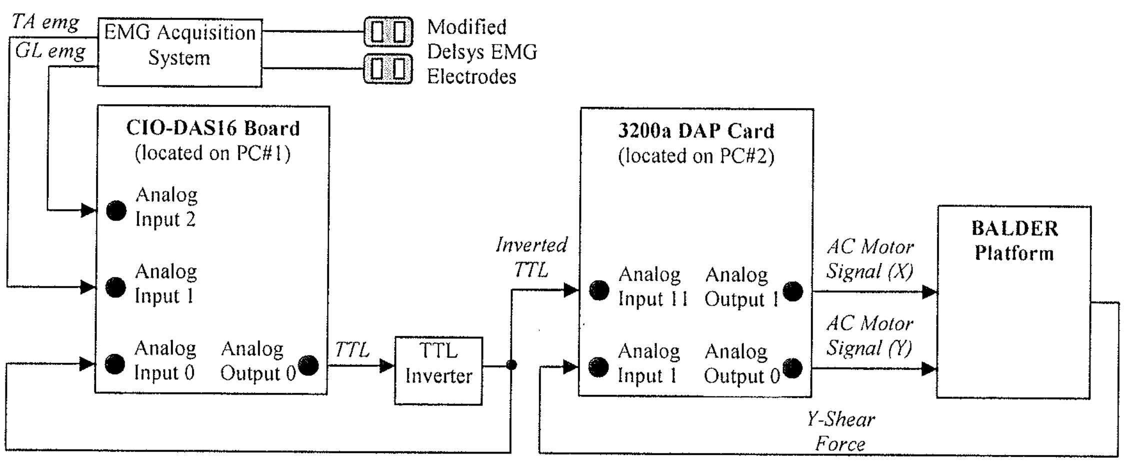


Figure 8: Diagram showing the physical connections and data flow for the equipment used in the simulated slip trials.

Two PCs were required for the setup of the simulated slips experiment. The first PC (PC#1) was used to initiate each simulated slip trial, and to record the EMG signals from the EMG Acquisition System. This PC was equipped with a Computer Boards, Inc. high speed data acquisition board (CIO-DAS16), consisting of a 16 channel A/D converter and a 2 channel D/A converter. The data acquisition board was controlled using a DasyLab 5.0 virtual lab interface. The second PC (PC#2) was used to control and record data from the BALDER platform. This PC was equipped with a MicroStar Laboratories 3200a Data Acquisition Processor (DAP) card. This DAP card contained a 16 channel A/D

converter, a 2 channel D/A converter, and an Intel i486 onboard processor. The DAP card was controlled by an existing Visual Basic virtual instrument panel that was used to create desired perturbation protocols. A perturbation consisted of a 5cm anteroposterior surface displacement with a maximum acceleration of $9.81 m/s^2$. A perturbation with these parameters has been shown to simulate a moderate [10].

The D/A channel 0 of the CIO-DAS16 board on PC#1 generated a TTL signal that was used to initiate the simulated slip trials. This TTL signal was inverted by a TTL inverting circuit, thus producing the signal required to externally trigger the BALDER platform. This trigger signal was sampled by both computers and later used to synchronize the two sets of data recorded for each simulated slip trial.

The EMG signals from the Tibialis anterior (TA) and Gastrocnemius lateral (GL) muscles were sampled by the CIO-DAS16 board on PC#1 at 1000Hz. The 3200a DAP card on PC#2 sampled the data from the force plate, the linear potentiometers, and the accelerometers in the BALDER platform at 100Hz. For this experiment, only the shear force measurements from the force plate in the anteroposterior (y) direction were needed. This data was used to determine the time of the onset of movement of the BALDER platform for a each simulated slip trial.

EMG Acquisition System

EMG signals from the TA and GL muscles were collected during the simulated slip experiment using a customized EMG acquisition system. Two DelSys shielded electrodes were modified to eliminate high frequency interference from AC motors that drove the BALDER platform. The signals from the electrodes were then sent to a pre-amplifier for signal conditioning. This process resulted in an overall signal gain of 1000, and a fixed bandwidth of 20-450Hz. The pre-amplifier also electronically isolated the subject from the setup for safety purposes. The processed EMG signals were then sampled at 1000Hz by the A/D converter on the CIO-DAS16 board on PC#1.

EXPERIMENTAL PROTOCOL

Quiet Standing Experiment

Ten healthy male and female subjects between the ages of 21 and 43 participated in the quiet standing experiment. The purpose of the experiment was to study the changes in postural behavior that occurred during quiet standing when vibrotactile feedback regarding the displacement of the COP under the feet was provided.

The time-varying displacement of the COP of the subject was measured during each trial using a Kistler portable force plate. The subjects stood on the force plate with their arms comfortably by their sides, and their bare feet in a standardized position. In the standardized position, the subjects' heels were

6cm apart and their feet abducted 10°. The FSR matrices were arranged on the force plate, for each subject, so that the subject's feet were in the standardized position when he or she stood on the matrices.

In preliminary testing sessions, it was observed that vibrotactile feedback of COP displacement induced a great deal of sway during bipedal quiet stance when it was presented to both legs. It was hypothesized that the feedback to both legs was too complex to be effective in a study that allowed the subjects only a brief period of training with the feedback system. To reduce the complexity of the feedback system, the vibrotactile feedback to the left leg was eliminated. The left FSR matrix was still placed under the subject's left foot to maintain a symmetrical feeling under the feet, but the data collected from the matrix was not used by the feedback program. The left leg vibrator array was not attached to the subject's left leg. The subject stood on the FSR matrices and wore the right leg vibrator array throughout the entire experiment, even during the control trials when feedback was not provided.

Each subject completed 10, 30 second quiet standing trials on the force plate in each of the following four conditions:

1. bipedal stance, eyes closed (control)
2. bipedal stance, eyes closed, vibrotactile feedback of COP displacement
3. unipedal stance, eyes open (control)
4. unipedal stance, eyes open, vibrotactile feedback of COP displacement

Subjects were given 30 seconds of rest between successive trials, and a 5 minute rest between each set of 10 trials. The control and vibrotactile feedback trials were alternated every two trials for both the bipedal and unipedal stances. This was done so that any effects of the subject's natural improvement of the task over time would appear equally in the control and vibrotactile feedback trials.

Prior to the recorded trials, each subject was given approximately 5 minutes to become accustomed to the vibrotactile feedback. The subjects were also given two 30 second practice trials with the vibrotactile feedback system. Subjects were instructed to not overreact when they felt one of the vibrators activate, but rather to attempt to use the feedback to maintain a steady body position. Subjects were instructed to stand as still as possible during all of the trials. Each trial was initiated following a verbal confirmation that the subject was prepared to begin the trial.

Simulated Slip Experiment

Two healthy male subjects between the ages of 21 and 35 were included in the simulated slips experiment. The purpose of this experiment was to study the changes in the postural responses of the subjects to simulated slips when vibrotactile feedback of the displacement of the COP under the feet was provided.

The activity of the TA and GL muscles in response to a simulated slip was measured using the EMG Acquisition System. Subjects stood on the BALDER platform with their eyes focused on a mark on the wall directly in front of them. At the beginning of each trial, the subjects stood with their arms comfortably by their sides and their bare feet in the standardized position for quiet stance. The FSR matrices were arranged on the BALDER platform, for each subject, so that the subject's feet were in the standardized position when he or she stood on the matrices.

In order to reduce the complexity of the feedback for the subject, only one vibrator, on the back of the right leg, was active. This meant that the subject only received vibrotactile feedback when his or her COP displacement increased in the posterior direction. Because of this constraint, the subject typically received vibrotactile feedback only during an anterior perturbation as his or her COP displacement increases in the posterior direction. The anterior perturbations were used for analysis of the postural responses of the subjects, while the posterior perturbations were included to randomize the direction of the perturbations. In order to become more familiar with the feedback system, each subject conducted approximately 45 practice simulated slips with the right leg, posterior vibrator providing feedback.

The first subject completed 6, un-cued simulated slip trials with vibrotactile feedback, and 6, un-cued simulated slip trials without vibrotactile feedback. The second subject completed 9 trial under each of the conditions. The subjects stood on the FSR matrices and wore the right leg vibrator array throughout the entire experiment, even during the trials in which feedback was not provided. The direction of the perturbation of each trial was determined randomly. Subjects were given approximately 30 seconds of rest between successive trials. Each trial was initiated following a verbal conformation that the subject was prepared to begin the trial, but the subject was not given a cue prior to the perturbation.

DATA ANALYSIS

Quiet Standing Experiment

In order to quantify the postural behavior of the subject population from the quiet standing experiment, 18 parameters were generated from each set of 10 trials. These parameters were then statistically analyzed across the subject population to determine any trends that occurred in the presence of vibrotactile feedback of the displacement of the COP under the right foot.

The data collected from the Kistler force plate was used to assess postural stability during the quiet stance trials. This force data was low-pass filtered at 15Hz using a 3rd order Butterworth filter, and used to calculate the time-varying displacement of the COP with a Matlab routine. The time-varying displacements of the COP in the mediolateral (x) and anteroposterior (y) directions from each set of 10

trials were then imported into the Stability Analysis System (SAS) software (Delsys Inc). This package automatically generated the stabilogram diffusion function in the mediolateral, anteroposterior, and resultant (r) directions for each 30 second trial. These functions were then averaged to attain a resultant stabilogram diffusion function in the three directions (x, y, and r) for each set of 10 trials.

Each resultant stabilogram diffusion function exhibited distinct short-term and long-term linear regions. The SAS software uses a modified version of the technique described in Collins and DeLuca, 1993 to determine the boundary between these two linear regions known as the critical point [8]. In this implementation, the time interval of the critical point was determined by locating the time interval corresponding to the first minimum of the second derivative of the averaged stabilogram diffusion function. The mean square displacement of the critical point is then the point on the averaged stabilogram diffusion vector corresponding to the critical point time interval. To calculate the diffusion parameters, the method of least squares is used to fit lines through the two linear regions on either side of the critical point time interval. The diffusion coefficients D are calculated from the slopes of the linear approximations of the two regions in each resultant stabilogram diffusion function. The scaling exponents H are calculated in a similar manner using the slopes of the log-log plot of the resultant stabilogram diffusion function.

Each resultant stabilogram diffusion function generated 6 parameters: the time interval and mean square displacement of the critical point, the diffusion coefficients of the short-term and long-term linear regions, and the scaling exponents of the short-term and long-term regions. These parameters were calculated from the averaged stabilogram diffusion plots in each of the three directions for each set of trials. Each set of 10 trials, therefore, generated 18 parameters for analysis.

The effect of the vibrotactile feedback on the postural behavior of the subject population was determined by comparing the values of each parameter generated from the trials with and without vibrotactile feedback across the population. Because the parameter values across the subject population could not be assumed to hold a normal distribution, a Wilcoxon signed-ranks test for nonparametric data was used to compare the parameters generated with and without the feedback.

Simulated Slip Experiment

In order to quantify the postural responses of the subjects from the simulated slip experiment, the latency between the onset of perturbation and the initiation of EMG activity from the TA muscle was calculated for each trial. The shear force in the anteroposterior direction provided an accurate measure of the onset of the perturbation because of the steep rise caused by the acceleration of the force plate with respect to the subject when the platform movement was initiated. The shear force was measured by the AMTI force plate imbedded in the BALDER platform. The anteroposterior shear force and EMG data

were not recorded on the same PC to prevent ground loop interference from the BALDER motors from severely distorting the EMG signals. A Matlab routine synchronized the data recorded from both PCs for each trial using the edge of the mutually-sampled trigger signal. The program then searched the anteroposterior shear force data for the first three consecutive values greater than 3.0N, and set the time value corresponding to the first of these points as the onset of the perturbation. This threshold of 3.0N was determined by inspection of several anteroposterior shear force recordings following perturbations. The same Matlab routine also determined the onset of the EMG activity. The activation of the motors of the BALDER platform created a low level of noise in the EMG recording that was easily distinguishable from the actual EMG signal. It was important, however, that the Matlab routine not choose this onset of noise as the onset of the EMG. The root-mean-square of the EMG (EMGrms) was calculated, and the onset of the EMG was determined by the time corresponding to the first value of the EMGrms that was greater than 0.0015. This threshold was chosen to be three times greater than the rms value associated with the noise of the motors (~ 0.0005). The latency of the subject's response to the perturbation was calculated as difference between the onset time of the EMG activity and the onset time of the perturbation. These delays were then statistically analyzed using a Wilcoxon signed rank test for each subject to determine any trends that occurred in the presence of vibrotactile feedback of the posterior displacement of the COP under the right foot.

RESULTS

Quiet Standing Experiment

In order to quantify the postural behavior changes that occurred during quiet standing due to the presence of vibrotactile feedback of the displacement of the COP under the right foot, the properties of the resultant stabilogram diffusion plots were compared.

Shown to the right are the stabilogram diffusion plots in the anteroposterior (y) and mediolateral (x) directions for both the control and vibrotactile feedback sets of bipedal quiet standing trials for three subjects (Figure 9). The stabilogram diffusion plots of these three subjects demonstrate the range of effects that the vibrotactile feedback system had on the postural behavior of the various subjects. The two lower curves on each plot are the stabilogram diffusion functions in the mediolateral direction, while the two upper curves are the resultant stabilogram diffusion plots in the anteroposterior direction. The fact that the mean square displacement in the anteroposterior direction was greater than the mean square displacement in the mediolateral direction is consistent with the results from similar studies on diffusion analysis of quiet standing, and simply reflects the fact that people sway more in the anteroposterior direction [9]. The results from the vibrotactile feedback can be observed by comparing the resultant stabilogram diffusion plots generated without feedback (shown in red) with the plots generated with feedback (shown in blue) in the corresponding direction. All subjects exhibited increases in the short-term diffusion coefficients during the presence of feedback, which is shown in

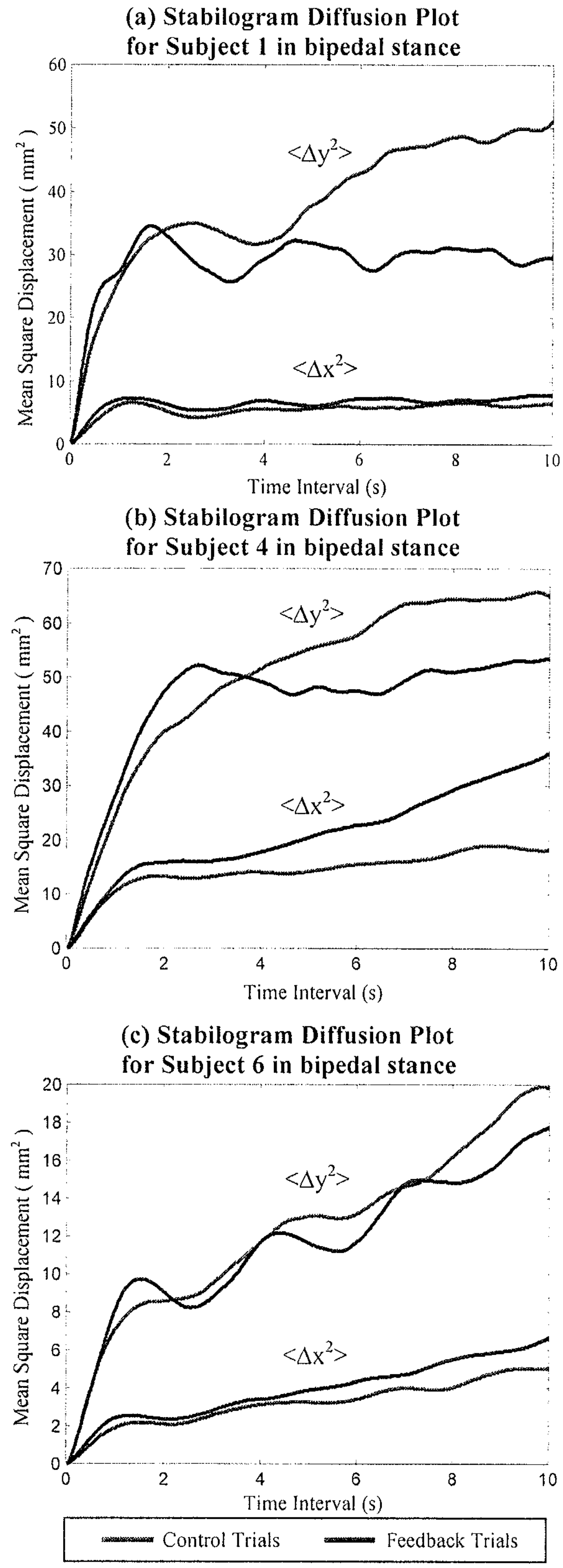


Figure 9: Stabilogram diffusion plots for Subjects 1, 4, and 6 generated from bipedal quiet stance with and without vibrotactile feedback of posterior COP displacement

Figure 9 by the blue curves rising more quickly than the red curves in the first linear regions. For Subjects 1 and 4, the long-term diffusion coefficients in the anteroposterior direction decrease in the presence of feedback. This is shown in Figure 9 by the decrease in the slopes of the long-term regions of the upper blue curves. For Subject 6, the decrease in diffusion coefficient in the long-term, anteroposterior direction is very small, and difficult to detect visually from the stabilogram diffusion plots. The long-term diffusion coefficient in the mediolateral direction increased with feedback for Subject 4, as shown in Figure 9 by the increase of the slope of the long-term region of the lower blue curve. The long-term diffusion coefficients in the mediolateral direction of Subjects 1and 6 also increased, but to a smaller degree than that of Subject 4. The sample subjects in Figure 9 were chosen to demonstrate the range of effects attribute to the use of the sensory substitution device. The effect on the entire subject population was highly significant.

Box and whiskers plots in Figures 10 and 11 describe the distribution of the parameters over the subject population and facilitate the comparison of the parameters values generated during the control trials and the vibrotactile feedback trials. A Wilcoxon signed rank test was performed on each corresponding set of control and vibrotactile feedback trials to determine whether the data sets were statistically different. The parameters in the planar direction (r) will not be discussed because they are simply the resultant of the anteroposterior and mediolateral parameters and therefore do not provide any additional information.

The short-term diffusion coefficients of the population in bipedal quiet standing significantly increased in both the anteroposterior and mediolateral directions during the vibrotactile feedback trials (Figure 10 a). The short-term diffusion coefficients of the population in unipedal quiet standing also increased significantly in both the anteroposterior and mediolateral directions during the vibrotactile feedback trials (Figure 10 b). It can be seen from the box and whiskers plots that the short-term diffusion coefficient in the anteroposterior direction appeared to have the most significant increase, which was verified by the Wilcoxon signed ranked test. The long-term diffusion coefficients in the anteroposterior direction decreased significantly in both bipedal and unipedal quiet standing during the presence of the vibrotactile feedback (Figure 10 c,d). The location of the critical point time interval (C_t) also decreased significantly in both directions during the vibrotactile feedback in the unipedal trials (Figure 10 f). Similarly, the location of the critical point mean square displacement in the anteroposterior direction increased significantly during the presence of the vibrotactile feedback during the unipedal trials (Figure 11 b). The anteroposterior long-term scaling exponents decreased significantly in the bipedal and unipedal quiet standing trials when vibrotactile feedback was presented (Figure 11 e,f). The remaining parameters did not change significantly as determined by the Wilcoxon signed rank test.

The values of the short-term and long-term diffusion coefficients for the unipedal quiet standing trials are greater than their bipedal counterparts in both directions. This result is expected due to the obvious instabilities caused by unipedal stance, but was not the concern of this study.

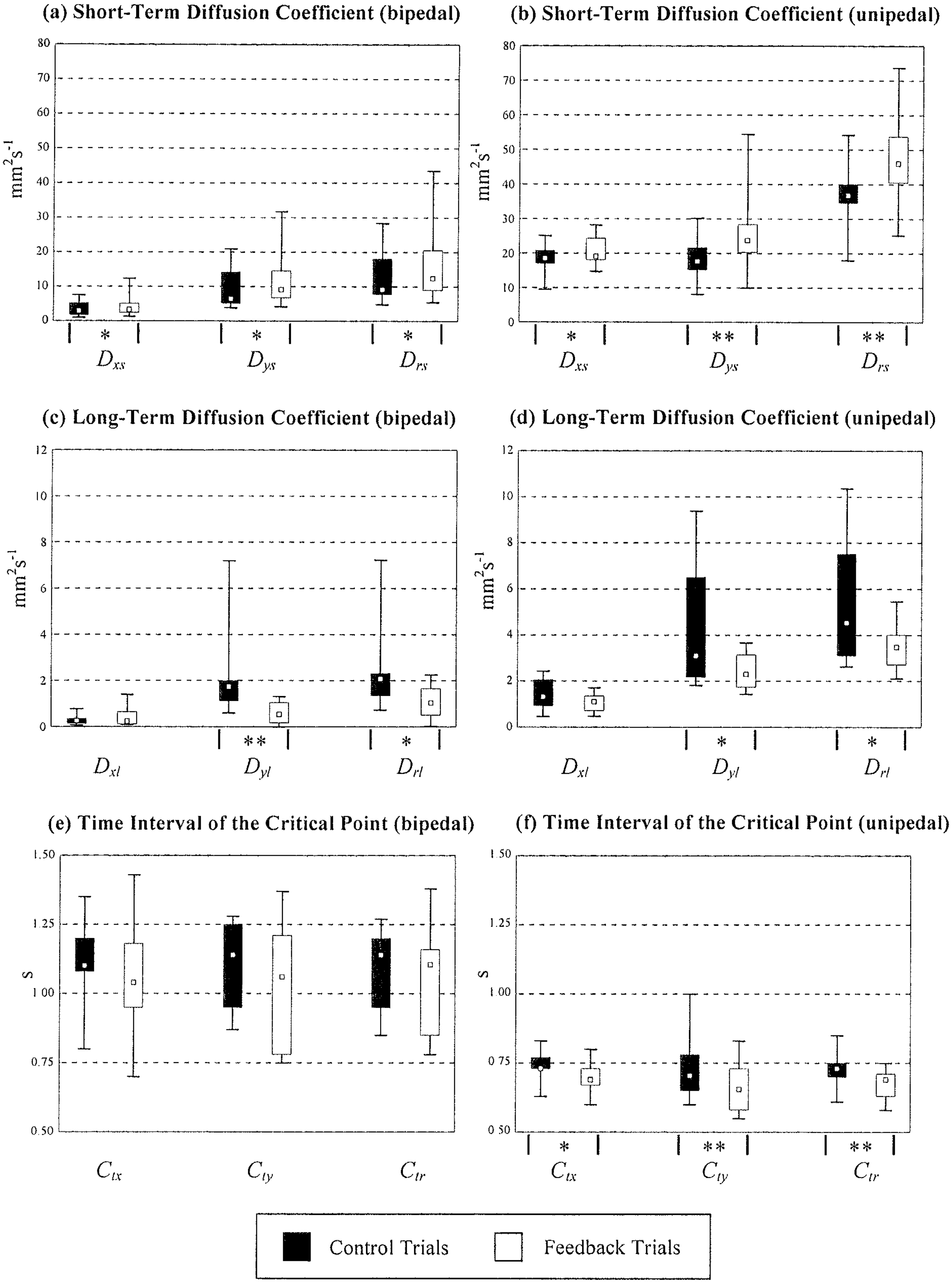


Figure 10: The top and bottom sides of the boxes represent the 75th and 25th percentiles of the parameter distribution respectively. The median of the distribution is represented by a small square marker within the box. The maximum and minimum values of parameters across the subject population are indicated by the lengths of the whiskers extending from the box in either direction. The black boxes represent these statistics for the control trials, while the white boxes represent these statistics for the trials during which vibrotactile feedback of the COP displacement was provided. Parameter differences that were determined to be statistically significant using a Wilcoxon signed rank test were indicated with a single asterisks for P<0.05 and a double asterisks for P<0.005.

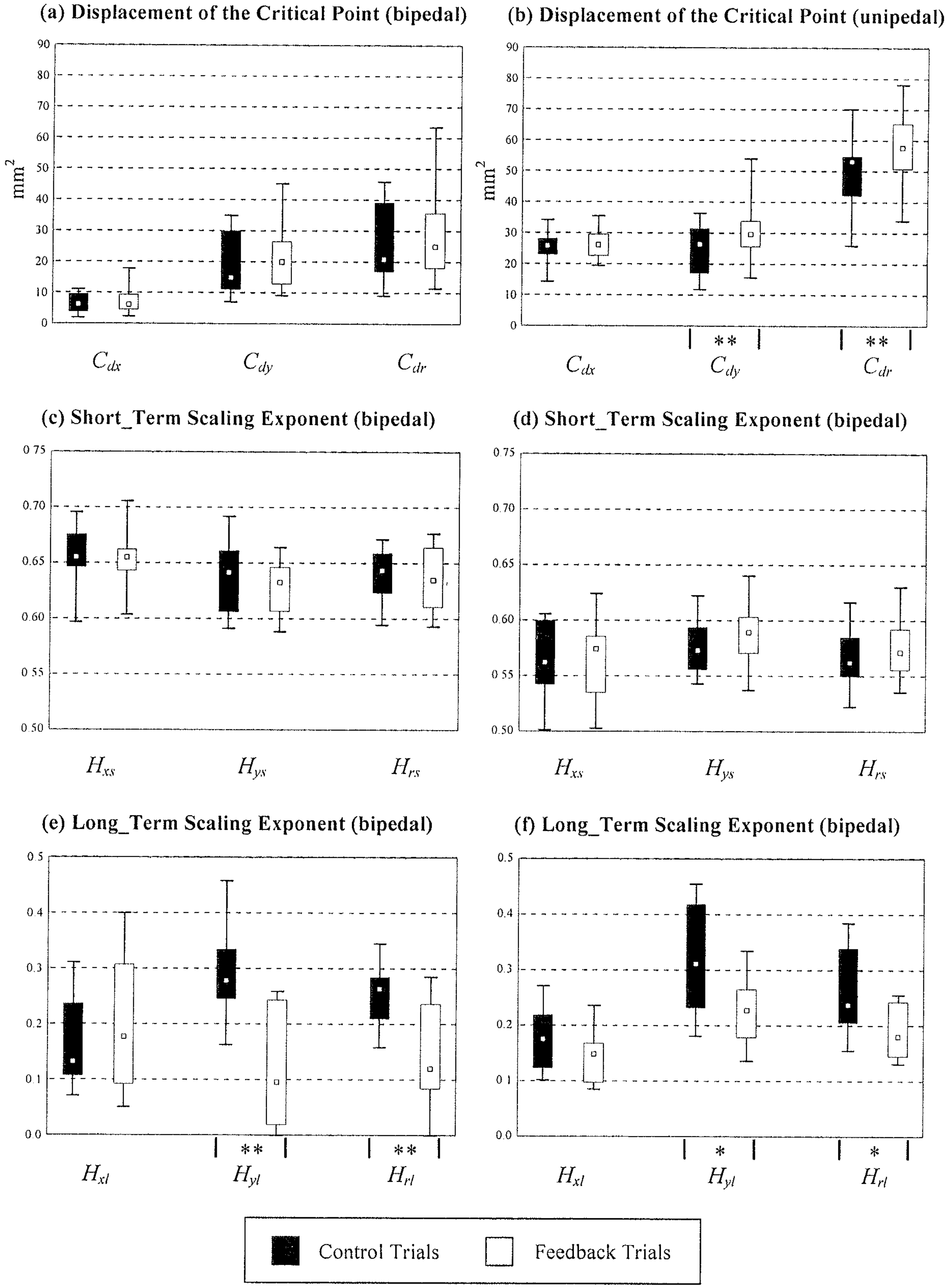


Figure 11: The top and bottom sides of the boxes represent the 75[th] and 25[th] percentiles of the parameter distribution respectively. The median of the distribution is represented by a small square marker within the box. The maximum and minimum values of parameters across the subject population are indicated by the lengths of the whiskers extending from the box in either direction. The black boxes represent these statistics for the control trials, while the white boxes represent these statistics for the trials during which vibrotactile feedback of the COP displacement was provided. Parameter differences that were determined to be statistically significant using a Wilcoxon signed rank test were indicated with a single asterisks for $P<0.05$ and a double asterisks for $P<0.005$.

Simulated Slip Experiment

The parameter used to quantify the postural response of the subject to the simulated slip was the delay between the onset of movement of the platform and the onset of the EMG activation from the Tibalis anterior (TA) muscle. The shear force recording from the force plate located on the BALDER platform was used to determine the onset of the movement of the platform. The TA muscle was chosen to indicate the response of the subject because it is the first muscle in the leg to respond to a forward perturbation in order to restore balance. The EMG Acquisition System used in this experiment was specially designed to record EMG during a movements of the BALDER platform. Prior to the activation of the motors, the EMG channel has practically no noise (Figure 12). Once the motors begin running to move the BALDER platform, a very low level of noise is present in the EMG channel. This level of noise is insignificant, however, when compared to the EMG signal recorded from the TA. The onset of the platform movement and onset of EMG are shown in Figure 12. The blue arrow indicates the length of the latency between the onset of platform movement and the onset of EMG, which was used as the measure of the subject's postural response for the simulated slips experiment.

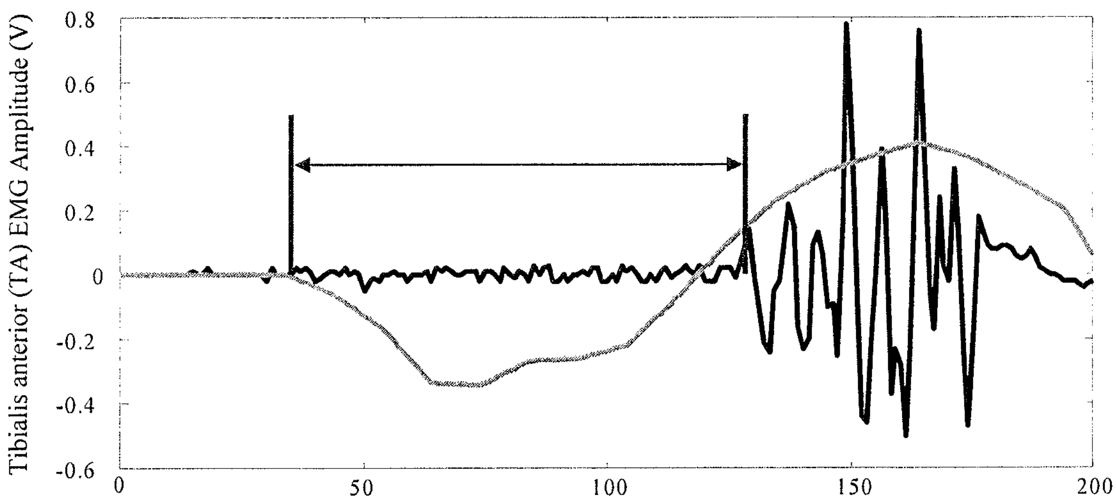


Figure 12: This plot shows the onset times of the anteroposterior shear force (first blue bar) and TA EMG (second blue bar) as calculated by the Matlab routine used for this experiment. The low level of noise in the EMG channel can be seen following the activation of the BALDER motors. The latency of the subject's response to the perturbation is the time interval between the blue bars.

While only two subjects were used in the simulated slip experiment, statistical analysis was used to determine whether the delays of the subjects were affected by the presentation of vibrotactile feedback of the displacement of the COP. A Wilcoxon signed rank test was performed on the control data and vibrotactile feedback data collected from both subjects to determine whether any changes in the delay

were statistically significant. Box and whisker plots were used to illustrate the distributions of the control data and vibrotactile feedback data.

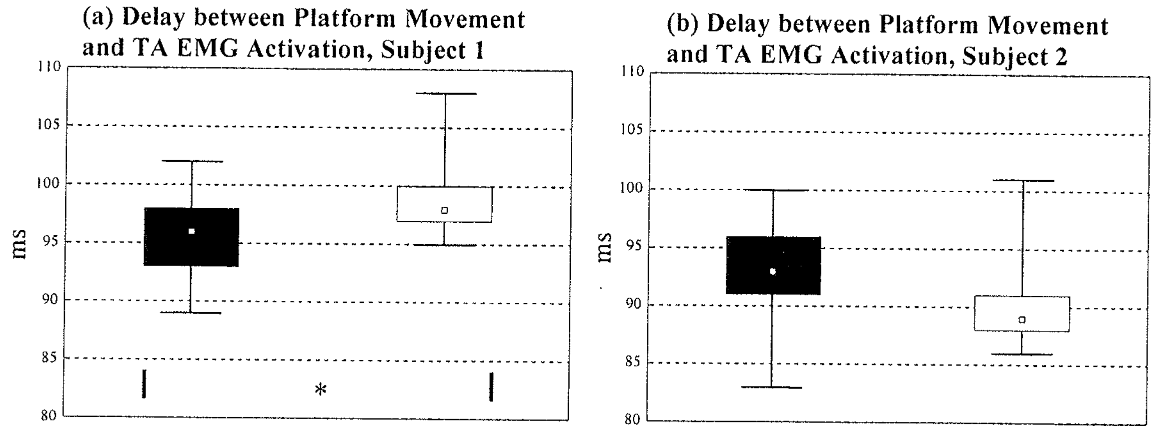


Figure 13: The top and bottom sides of the boxes represent the 75th and 25th percentiles of the parameter distribution respectively. The median of the distribution is represented by a small square marker within the box. The maximum and minimum values of parameters across the subject population are indicated by the lengths of the whiskers extending from the box in either direction. The black boxes represent these statistics for the control trials, while the white boxes represent these statistics for the trials during which vibrotactile feedback of the COP displacement was provided.

The delay between the onset of platform movement and the onset of TA EMG for Subject 1 was shown to statistically increase in the presence of vibrotactile feedback of the displacement of the COP (Figure 13 a). The response delay for Subject 2 did not have any statistically significant differences in the presence of the vibrotactile feedback (Figure 13 b).

DISCUSSION

Statistical analysis of the quiet standing trials in which vibrotactile feedback of the displacement of the COP under the right foot was provided to the right leg revealed several differences in the diffusion coefficients. In the short-term region, the diffusion coefficients increased significantly in the anteroposterior and mediolateral directions for bipedal and unipedal stances during the presence of the vibrotactile feedback (Figure 10 a,b). The diffusion coefficient is the average measure of stochastic activity of the COP displacement, which has been modeled as a random walker. These results indicate that the vibrotactile feedback of COP displacement increased the stochastic activity in the short-term region [8]. One possible explanation for this occurrence is that the vibrotactile feedback system caused the subjects to increase their baseline level of muscle activity to attempt to keep their COP in the threshold region. This increased level of muscle activity would cause the short-term movements of the subjects to become more stochastic due to the random noise associated with muscle force production. In

the long-term region, the diffusion coefficients decreased significantly in the anteroposterior direction for both bipedal and unipedal stance during the presence of the vibrotactile feedback (Figure 10 c,d). This result appears to indicate that vibrotactile feedback of the COP displacement decreased the stochastic activity in the long-term region. This result might be due to the increased stiffness and muscle activity that was induced by the vibrotactile feedback. This heightened level of muscle activity may have instituted tighter control of the long-term region of COP displacement. If this is true, the large, anti-persistent drifts that are characteristic of normal quiet standing might have been eliminated by the vibrotactile feedback system. It appears that the vibrotactile feedback system agitated the short-term region of posture control (possible due increased muscle activity), but had a stabilizing effect on the long-term region of posture control (less large drifting effects).

SUMMARY AND RECOMMENDATIONS

The sensory substitution system investigated in this study successfully elicited postural responses from a population of healthy subjects during quiet standing. The experiment to determine whether the sensory substitution system was able to alter the postural responses to a simulated slip was inconclusive due to the small number of subjects and the lack of training.

Because the sensory substitution system was able to elicit postural responses in healthy subject, it appears likely that the system could someday provide essential postural stability to patients suffering from sensory deficiencies such as peripheral neuropathy.

Future testing of this sensory substitution system should be directed at testing the device on healthy subjects with induced sensory loss (i.e. foot sole anesthetization), and eventually toward testing patients with peripheral neuropathies.

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Other University ref. #:

Exhibit D

1. Title of Invention:
Sensory Prosthetic for Improved Balance Control

2. Inventor(s) Information:

Name(s)	Position Title(s)	School/Department or Collaborating Organization	Telephone Number
Peter F. Meyer	Graduate Research Assistant	NeuroMuscular Research Center & Department of Biomedical Engineering	353-9638
Lars I. E. Oddsson, Dr. Med. Sci.	Research Associate Professor	NeuroMuscular Research Center	358-0717

3. Sponsorship Information: Either: I Confirm No Grant Funds Were Used ⇒ Signed:

Or: Supply details here ⇒	Grant/Contract No.	BU Source No.	Principal Investigator	Agency	Grant Admin.

4. Events:

	Event Description:	Date:	Location:	References & Comments:
A.	First description of complete invention, oral or written (*conception*)	May 22, 1999	NeuroMuscular Research Center 44 Cummington Street, Boston MA	Initial meeting of inventors to discuss a "mechanoreceptor prosthetic for balance control in peripheral neuropathy patients"
B.	Invention development records, notes, drawings (Evidence of *diligence*)	May 22, 1999 to present	NeuroMuscular Research Center 19 Deerfield Street, Boston MA	Development records detailed in laboratory notebook including dates, discussion notes, and sketches.
C.	First successful demonstration, if any (first actual *reduction to practice*)	March 24, 2000	NeuroMuscular Research Center 19 Deerfield Street, Boston MA	Prototype completed. Subsequent testing demonstrated efficacy
D.	First publication containing full description of invention (*publication bar* established)	none		

E. External disclosures (in the past, or expected in the future, with date)
BME Undergraduate Senior Project of Nicholas Patronik. Study involving testing of device, April 28, 2000. Project report submitted to Professor Ken Lutchen, not available to public
BME Undergraduate Senior Project Presentation by Nicholas Patronik, May 5, 2000. Public presentation of testing results. Unique features of device not disclosed.
Master's thesis of Mats Freding, Royal Institute of Technology, Stockholm. Construction of prototype device. Expected completion of thesis in Fall 2000. We have requested that thesis presentation be closed to the public.

I (We) hereby agree to assign all right, title and interest to this invention to Boston University and agree to execute all documents as requested, assigning to Boston University our right in any patent application filed on this invention, and to cooperate with the Boston University Office of Technology Transfer in the protection of this invention. Boston University will share any royalty income derived from the invention with the inventor(s) according to its standard policies.

Inventor's Signature
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Country of Citizenship

Inventor's Signature
10/23/00
Date
905 Beacon Street
Home Address
028-76-6434
Social Security Number (required)
Iceland
Country of Citizenship

Please attach the following (both hard and electronic copies):
- detailed description of the invention;
- A two or three sentence, non-confidential description of its usefulness;
- A one page non-confidential description of its usefulness;
- A list of Potential licensees.

6. Technology Disclosed to and understood by:

Gerald Gottlieb
Name of Non-inventor Witness

Signature of Non-inventor Witness

SHORT, NON-CONFIDENTIAL DESCRIPTION OF USEFULNESS

A portable feedback device has been invented which measures information related to the balance of a person while walking or standing and produces a stimulation of the skin which encodes that information. The device could be used to improve balance in patients suffering from deficits in foot sole cutaneous sensation or to produce an artificial feeling of pressure under the feet for integration into virtual environments. In addition, the device could be used to provide cutaneous foot sole stimulation to bedridden patients or astronauts in a microgravity environment, thereby reducing balance deficits related to long-term adaptation to these conditions.

NON-CONFIDENTIAL DESCRIPTION OF USEFULNESS

It has been estimated that as high as 20% of the elderly population in the United States may be suffering from peripheral neuropathies, largely as a consequence of diabetes (1). Peripheral neuropathic patients exhibit increased body sway during quiet standing (2). Peripheral neuropathies have been associated with increased thresholds for the perception of ankle inversion/eversion (3) and a reduced ability to maintain a unipedal stance (4), suggesting a reduction in balance control while walking. Epidemiological evidence has linked peripheral neuropathies with an increased risk of falling (1, 5). Postural responses to floor perturbations in peripheral (diabetic) neuropathy patients are delayed and are poorly scaled to the perturbation amplitude (6).

The most common symptom of peripheral neuropathies is a reduction in sensation from the soles of the feet. A number of studies have provided evidence that afferent information from the feet is an important part of the balance control system (7, 8, 9, 10, 11, 12). A recent study on adaptation to microgravity suggests that foot sole pressure may be critical for triggering the anticipatory postural adjustments that are normally required to maintain balance during arm movements (13). An investigation is currently underway at the NeuroMuscular Research Center to quantify the specific role played by foot sole cutaneous afferents in balance control under both static and dynamic conditions.

A sensory substitution system has been invented which provides information regarding foot sole pressure distribution to patients who are no longer able to acquire this information by natural means. A patient wearing this device will achieve improved upright balance control, reducing their risk of falls and associated injuries. With practice, this information will be integrated into the patients unconscious postural control system and no longer require conscious effort. An alternative embodiment of the device may reduce the balance deficits caused by prolonged exposure to reduced weight bearing, as seen in patients recovering from prolonged bed rest or in astronauts returning to terrestrial gravity. Preventative treatments with this device should reduce the hypersensitivity of the foot soles which contributes to these postural deficits.

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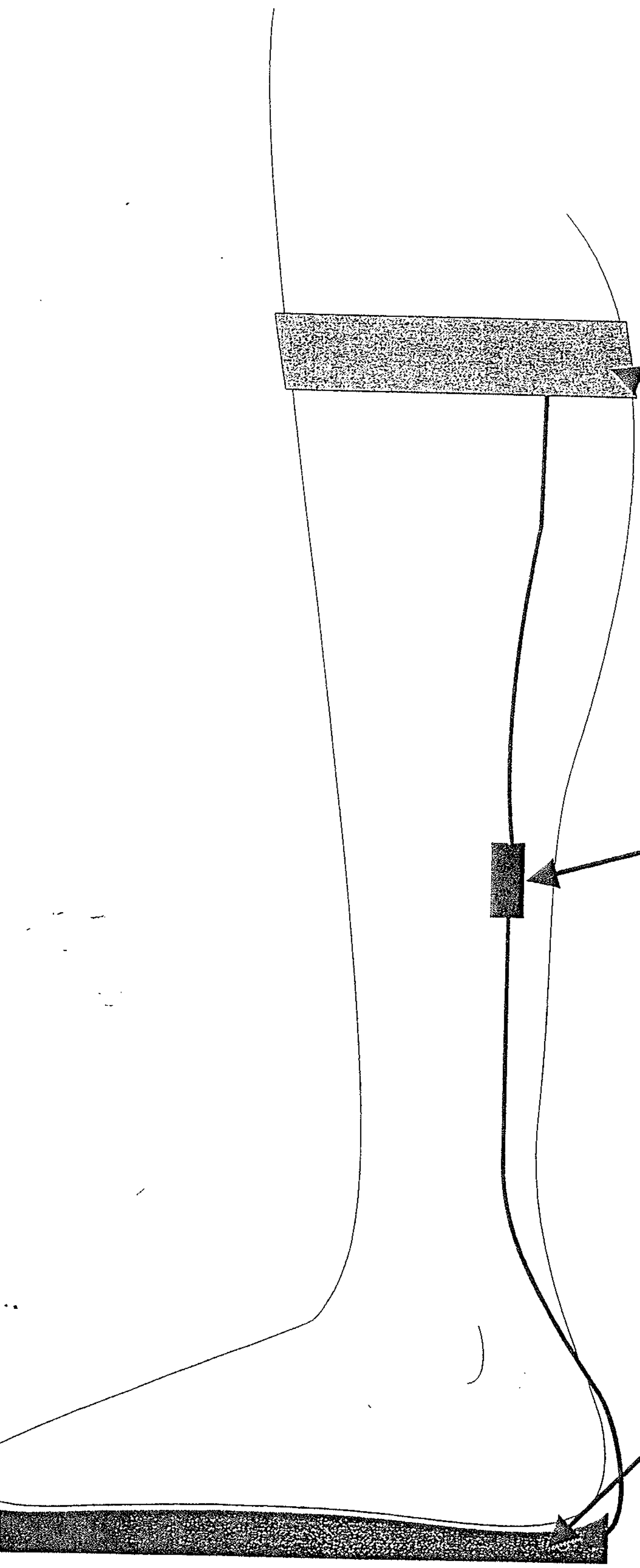
Preferred Embodiment Shown



Uses: Improving static and dynamic balance control, especially in patients suffering from reduced plantar pressure sensation; simulation of balance conditions (Virtual Reality); stimulation of plantar pressure receptors to reduce adverse adaptations to reduced weight bearing (i.e. prolonged bedrest or microgravity exposure).

1) Feedback Array:
Vibrotactile or electrotactile cutaneous feedback encodes position of foot Center-Of-Pressure and/or weight distribution by modulating one or more of the following: stimulus frequency, stimulus amplitude, location of stimulus or number of active stimulators. This Element(s) is located adjacent to the skin of the leg or thigh. The location of active stimulator(s) on the skin in the transverse plane will directly reflect the location of the foot Center-of-Pressure in the transverse plane.

2) Signal Processor/Controller:
Converts electrical or mechanical signal(s) from Planta Pressure Sensor Array into signal(s) which control the activity of the Feedback Array element(s). May be implemented as a discrete system component or be imbedded within the Plantar Pressure Sensor Array or Feedback Array. Performs an estimation of the position of the Center-of-Pressure under the foot and/or the fraction of body weight supported by the foot. These estimates are then used to produce an appropriate output signal to the Feedback Array. A "dead-zone" may be implemented such that Center-of-Pressure position within a certain range and/or foot load below a certain threshold may produce no output to the feedback elements.

3) Plantar Pressure Sensor Array: Transduces pressure distribution under the foot and transfers that information to the Signal Processor/Controller.

edal Device; only one leg shown. One or more of modules may be against the skin in a stocking. Sensor array module may be rporated into a shoe or implemented as a shoe insert. Connection veen modules may be wireless. Feedback elements may be rporated into a a shoe or shoe insert.

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SENSORY PROSTHETIC FOR IMPROVED BALANCE CONTROL

INTRODUCTION

A portable feedback device is disclosed which measures information related to the balance of a person while walking or standing and produces a stimulation of the skin that encodes that information. The device could be used to improve balance in patients suffering from deficits in foot sole cutaneous sensation or to produce an artificial feeling of pressure under the feet for integration into virtual environments. In addition, the device could be used to provide cutaneous foot sole stimulation to bedridden patients or astronauts in a microgravity environment, thereby reducing balance deficits related to long-term adaptation to these conditions.

GENERAL PURPOSE

It has been estimated that as high as 20% of the elderly population in the United States may be suffering from peripheral neuropathies, largely as a consequence of diabetes [13]. Peripheral neuropathic patients exhibit increased body sway during quiet standing [2]. Peripheral neuropathies have been associated with increased thresholds for the perception of ankle inversion/eversion [14] and a reduced ability to maintain a unipedal stance [11], suggesting a reduction in balance control while walking. Epidemiological evidence has linked peripheral neuropathies with an increased risk of falling [12, 13]. Postural responses to floor perturbations in peripheral (diabetic) neuropathy patients are delayed and are poorly scaled to the perturbation amplitude [4].

The most common symptom of peripheral neuropathies is a reduction in sensation from the soles of the feet. A number of studies have provided evidence that afferent information from the feet is an important part of the balance control system [1, 3, 5, 6, 8, 9]. A recent study on adaptation to microgravity suggests that foot sole pressure may be critical for triggering the anticipatory postural adjustments that are normally required to maintain balance during arm movements [7]. An investigation is currently underway at the NeuroMuscular Research Center to quantify the specific role played by foot sole cutaneous afferents in balance control under both static and dynamic conditions.

The device disclosed here is a sensory substitution system that provides information regarding foot sole pressure distribution to patients who are no longer able to acquire this information by natural means. A patient wearing this device will achieve improved upright balance control, reducing their risk of falls and associated injuries. With practice, this information will be integrated into the patients unconscious postural control system and no longer require conscious effort.

DESCRIPTION OF THE DEVICE

The preferred embodiment of the device consists of three parts:

a) An array of sensors arranged under the soles of each foot which transduce the magnitude of pressure exerted on the foot sole at each sensor location.

b) A signal processor that converts the signal obtained from each pressure transducer into estimates of the location and magnitude of the resultant ground reaction force exerted on each foot (center-of-pressure, or COP). The signal processor then encodes the estimate of COP into signals that drive elements of the stimulator array.
c) An array of vibrotactile stimulators that are placed upon the leg in a plane approximately parallel to the plane of the foot sole in four locations on each leg: anterior, posterior, medial, & lateral. In response to signals produced by the signal processor, the array provides vibrotactile stimulation of the skin of the leg.

A simple diagram of the preferred embodiment is attached.

Using this portable, wearable device, the subject receives cutaneous stimulation on the leg regarding the location and magnitude of the ground reaction force under the ipsilateral foot. With training, a patient suffering from reduced plantar sensation will learn to make postural corrections in response to this stimulation in the same manner as a healthy person would react to changes in the pressure distribution under their feet.

ADVANTAGES AND IMPROVEMENTS OVER EXISTING DEVICES

To our knowledge, there are no commercially available sensory substitution devices designed to improve postural balance. The device disclosed here is similar to the device described in US Patent 4760850 (expired; see below). It possesses a number of advantages over US4760850, including:

a) The simplification of the feedback such that it can more easily be integrated into the unconscious postural control system. The reduction of individual pressure signals to an estimate of COP position and magnitude under each foot is easier to integrate into the postural control system than information regarding a number of separate pressure transducers.
b) The coding of information using frequency modulation rather than amplitude modulation. Cutaneous stimulation has been shown to excite cutaneous mechanoreceptors on a 1 to 1 basis for a wide range of input frequencies. As a result, some cutaneous mechanoreceptors will respond to an artificial stimulation (vibrotactile or electrotactile) in the same manner as they would respond to a pressure stimulus. Simulating a natural pressure stimulus with an artificial one in this manner should facilitate the integration of this information into the unconscious balance control system.
c) The location of feedback on the legs and oriented in a plane parallel to the plane of the foot sole should facilitate the integration of feedback information into the unconscious balance control system.
d) The explicit purpose of this device is for improved balance control in patients suffering from reduced foot sensation. The claims in US4760850 only refer to use by patients with injured spinal cords. While not mutually exclusive, the target population for this work is significantly larger than that described by the previous patent.

U.S. Patent 5878378 describes a training device integrated into a ski boot that provides a signal to the wearer that the pressure difference between force sensing resistors under the

forefoot and rearfoot has exceeded a threshold value. The device disclosed here has a number of advantages over this device:

a) The previous device only communicates to the wearer whether or not the fore-aft pressure distribution exceeds a threshold. The current device provides feedback regarding both the magnitude of this pressure difference and the magnitude of the total pressure under each foot.
b) Feedback is provided in the medial-lateral direction as well as the anterior-posterior direction.
c) The previous device was intended for training purposes only. The current device is intended to be worn as a prosthetic for continuous everyday use.

U.S. Patent 5919149 describes a device mounted on the torso that senses body lean and provides feedback to the user regarding body angle, angular velocity, or angular acceleration. In contrast, one variation of the disclosed device includes a transducer that senses and provides feedback regarding the angle and/or angular velocity of the ankle joint only. It is important to note that the angle of body "lean" and the angle between the foot and the shank are very different.

U.S. Patent 5221088 describes a sports training device that provides auditory feedback regarding the distribution of body weight between the feet or between two sites under each foot. The device disclosed here embodies a number of improvements:

a) US5221088 is specifically intended for training purposes. The device disclosed here is intended to be used as a balance aid for use during activities of daily living.
b) US5221088 describes the use of auditory cues to give information regarding weight distribution to the wearer. These cues can be expected to be distracting and interfere with the normal hearing of the wearer. The preferred embodiment of the device disclosed here uses feedback on the skin of the leg, a sensory area that is not normally used for other activities.
c) US5221088 provides no information regarding the medial/lateral distribution of body weight under each foot. This information may be very important to balance control while walking.
d) US5221088 describes a feedback signal that changes as the sensor signal reaches a threshold. In the device disclosed here, the feedback stimulus is a continuous function of the sensor signal, providing much greater resolution.

U.S. Patent 3751733 describes a means to transduce pressure and/or temperature from a prosthetic limb and provide feedback to the limb stump. An alternative embodiment of the device disclosed here has an advantage over US3751733 in that the feedback provided represents the Center-of-Pressure under a prosthetic foot, rather than the pressure at one or more location. This reduction of information may be crucial to the integration of feedback into the unconscious balance control system.

POSSIBLE VARIATIONS AND MODIFICATIONS

1. The sensor array and/or feedback array are incorporated into a stocking, shoe, or boot.

2. The device acquires, encodes, and provides feedback regarding shear forces under the foot.
3. The device acquires, encodes, and provides feedback regarding angle and or angular velocity of the lower leg with respect to the foot.
4. The device stimulates the cutaneous foot sole for the purpose of reducing postural deficits associated with long-term exposure to reduced foot loads, such as those incurred by bedridden patients on earth or astronauts in microgravity.
5. The device stimulates the cutaneous foot sole for the purpose of producing an artificial feeling of pressure or shear force, such as might be used in virtual environments.
6. The device stimulates the skin of a part of the body other than the foot sole for the purpose of producing an artificial feeling of pressure or shear force, such as might be used in virtual environments.
7. The device stimulates the cutaneous foot sole in response to pressure under the foot for the purpose of amplifying the sensation of pressure.
8. The implementation of a signal processing method such that a range of COP positions and/or magnitudes produce no output from the feedback array (i.e. sensory "dead zone").
9. The mode of feedback is tactile, vibrotactile, electrotactile, visual, thermal, and/or auditory.
10. The sensor array is implanted into or under the skin or within the body.
11. The feedback array is implanted into or under the skin or within the body.
12. The feedback array is implanted such that the feedback elements are adjacent to or in contact with one or more sensory neurons or sensory nerves.
13. The sensor array is affixed to or embedded within a prosthetic limb.
14. The connection between any or all of the device components is wireless.
15. The sensor signals and/or feedback signals are monitored remotely or recorded for the purpose of evaluating the effect or function of the device.

FEATURES BELIEVED TO BE NEW

1. Conversion of pressure information from multiple sensors located on the foot sole to a single measure of Center-of-Pressure. This simplified feedback should be more easily integrated into the balance control system than feedback encoding the pressure distribution directly.
2. Feedback of location of center-of-pressure under each foot in both anterior/posterior and medial/lateral directions. Sensation of medial-lateral direction may be particularly important for balance control during walking, which involves repeated periods of unipedal stance.
3. Location of feedback stimulators on the legs, arranged in a plane parallel to that of the foot sole. This may facilitate sensory integration into normal balance control.
4. Encoding of postural information by means of modulating the frequency of electrotactile or vibrotactile stimulators within a feedback stimulation array. This type of stimulation will more closely approximate the normal sensation of pressure, since greater amplitudes of pressure on the skin normally result in greater firing frequency in cutaneous mechanoreceptors.

5. Implementation of a feedback system that incorporates a range of input stimuli that produce no output to the feedback array (sensory dead-zone). This is based upon the theory that normal posture control may involve mechanisms that are insensitive to sensory feedback as well as those that rely on sensory feedback. This claim could potentially conflict with Claim 1 of U. S. Patent 5878378.
6. The variation that includes the acquisition of foot-sole shear force information and feedback of this information to the wearer (tactile, electrotactile, vibrotactile, visual, thermal, or auditory feedback). This feedback would provide information regarding the stretch of the foot sole skin and be used to sense slipping of the foot with respect to the support surface.
7. The variation that includes one or more modes of feedback (tactile, vibrotactile, electrotactile, visual, thermal, auditory).
8. The variation that includes acquisition of ankle angle information (plantar/dorsiflexion and/or inversion/ eversion) and feedback of this information to the wearer using electrotactile, vibrotactile, visual, thermal, or auditory feedback.
9. The variation that includes the acquisition of shear force information from the foot sole and feedback of this information to the wearer using electrotactile, vibrotactile, visual, thermal, or auditory feedback.
10. The variation that includes the integration of information regarding the location of center-of-pressure, total limb load, ankle angle, and/or shear force under each foot into signals that drive the feedback array.
11. The variation that includes the location of vibrotactile or electrotactile feedback stimulators on the soles of the feet to produce an effective amplification of sensation from the cutaneous foot sole. Such a system might compensate for reduced plantar sensation without requiring stimulation of a skin area that is not normally involved in balance control. In addition, such a system might be useful in a microgravity environment. Foot sole pressure sensors appear to be important to the triggering of normal anticipatory postural responses that precede activities that perturb the center of mass, such as arm raises. By amplifying the sensation of pressure under the feet, these anticipatory responses may be triggered even in a microgravity environment. While such responses may be unnecessary in microgravity, maintaining these reflexes throughout space flight may accelerate the re-adaptation to terrestrial gravity upon return to earth. This claim is similar to, but does not conflict with Claims 4, 6, 8, & 9 of BU held U.S. Patent 6032074 and Claims 1c, 6, 11, 16, & 17 of BU held U.S. Patent 5782873. These previous patents described the reduction of sensory thresholds by the introduction of a bias signal. In the current device option, sensation is improved by the amplification of the pressure stimulus to the foot while the foot sole cutaneous mechanoreceptor sensory thresholds remain the same.
12. The variation that includes the location of vibrotactile or electrotactile feedback stimulators on the soles of the feet to stimulate the cutaneous sensory receptors of the foot sole. This "exercise" of foot sole sensation may reduce the hypersensitivity of the foot sole normally seen after prolonged periods of reduced weight bearing and improve balance control following a return to normal weight bearing.
13. The variation that includes the stimulation of the cutaneous foot sole in order to provide a false feeling of pressure or movement under the feet. This stimulation

would evoke automatic postural responses which would be useful in establishing a feeling of "presence" in a virtual environment.

14. The variation that includes the cutaneous stimulation of parts of the body other than the foot sole, such as the buttocks or back, in order to simulate changes in pressure applied to that area. This stimulation would evoke automatic postural responses which would be useful in establishing a feeling of "presence" in a virtual environment. This variation would be particularly when the subject is sitting within a virtual environment, such as in flight simulator. In this case, cutaneous stimulation may reduce the physical movements of a simulator required to produce a desired sensation.
15. The variation in which the sensor array and/or feedback array are implanted under the skin or within the body.
16. The variation in which the feedback array elements are implanted within the body adjacent to or in contact with sensory neuron(s) or nerves.
17. The variation in which the sensor array is affixed to or embedded within a prosthetic limb. This would provide sensation of load, pressure distribution, shear force, or "ankle" angle that would not normally be available to the wearer.
18. The variations in which the sensor array, feedback array, or both are implanted under the skin or within the body. This would provide a permanent means of obtaining feedback information no longer available to the patient.

CLOSE OR RELATED PATENTS

The following are patents believed to be related to the current device. Specific clauses believed to be particularly related are highlighted in boldface. In addition, two devices described in scientific journals but not patented are summarized.

Phillips, C. A. (1988) Method for Balance Assistance. Wright State University, Dayton OH, US Patent 4760850. **Expired 1996**

Abstract: Method for assisting in the maintenance of a balanced stance by a person who has **lost the sense of touch in one or both feet**. Load signals are generated in correspondence with body weight loads applied at forward and rearward portions of the feet. The load signals are used for creation of tactile stimuli in a spaced pattern on a sensitive skin area of the person.

What is claimed is:

1. Method of assisting a **spinal-cord-injured person** to maintain a balanced stance comprising the steps of: securing braces to both legs of said person, generating **four balance signals corresponding to the loads created by the weight of said person at forward and rearward portions of both feet**, applying **tactile stimuli corresponding to said balance signals** in a spaced pattern on a sensitive skin area of said person for enabling said person to maintain a balanced stance.
2. Method according to claim 1 wherein the step of applying includes applying said tactile stimuli at the corners of a square having sides approximately four inches long.
3. Method according to claim 2 wherein said stimuli are **vibrational stimuli**.

4. Method according to <u>claim 1</u> wherein said balance signals includes the step of causing signals to oscillate at **fixed frequencies** in a range between about 5 Hz and 500 Hz and have **peak amplitudes which vary in correspondence with variations in said loads**; said tactile stimuli being generated by causing vibration of mechanical receptor elements in correspondence with variations in said balance signals.
5. Method according to <u>claim 4</u> and comprising the further step of causing all of said stimuli to have relatively low and comfortable reference levels when said person has achieved a balanced stance.
6. Method according to <u>claim 4</u> and comprising the further step of **causing said stimuli to discontinue when their corresponding loads are reduced to zero**.

Brommer, K. D., P. J. Schibly and T. G. Hebert (1999) Boot balance training device. Mountain Dynamics, Inc., Hampton Falls, NH, US Patent 5878378.

Abstract: A balance training device for sports such as skiing and skating uses force sensors located to sense forward pressure between a boot and the wearer thereof and electrical components to generate immediate feedback to the wearer.

What is claimed is:

1. A foot balance training device, comprising:
   - **first and second force sensitive resistors;**
   - means for affixing the first and second force sensitive resistors for sensing **forward pressure** exerted between a person's foot or leg and footwear means being worn by the person with the first force sensitive resistor, and for sensing **rearward pressure** exerted between the foot or leg and the footwear means with the second force sensitive resistor;
   - means responsive to the first and second resistors for **comparing the forward and rearward pressure sensed by the first and second resistors** by comparing resistance values of the first and second resistors, **including threshold means for determining a threshold difference value by which the resistance values of the first and second resistors are compared**; and
   - signal means responsive to the means for comparing for **communicating to the person wearing the footwear means the greater of either the forward or rearward pressure sensed by the first and second resistors in relation to the threshold difference value.**
2. The training device of <u>claim 1</u>, wherein the footwear means is a ski or snow board and the first and second force sensitive resistors are affixed between the ski or snow board and a boot worn by a user of that ski or snow board.
3. The training device of <u>claim 2</u>, wherein the resistors are affixed between a ski and a ski binding.
4. The training device of <u>claim 2</u>, wherein the resistors are affixed between a ski boot and a ski binding.

5. The training device of claim 1, wherein the means for affixing includes a shoe insole adapted to locate the first and second force sensitive resistors under ball and heal portions of a human foot.
6. The training device of claim 1, wherein the means for affixing includes an elastic band adapted for wear around a person's leg between the leg and an upper portion of an athletic boot, and further wherein the first force sensitive resistor is affixed to the elastic band at a location adapted for wear at a front portion of the person's leg and the second force sensitive resistor is affixed to the elastic band at a location adapted for wear at a rear portion of the person's leg.
7. The training device of claim 1, wherein the first and second force sensitive resistors are affixed to upper portions of a boot collar of the footwear means and further wherein the first force sensitive resistor is affixed at a front portion of the person's leg and the second force sensitive resistor is affixed at a rear portion of the person's leg.
8. The training device of claim 7, wherein the footwear means is a ski boot or skate boot.
9. The training device of claim 1, wherein the threshold means is adapted for adjustment during use of the device.

Collins, J. J. (1998) US Patent 5782873: Method and apparatus for improving the function of sensory cells. Trustees of Boston University, Boston, MA, US.

Abstract: Method and system for enhancing the function of sensory cells are disclosed. The method comprises locating a sensory cell area associated with the sensory cell whose function is to be enhanced and inputting a bias signal to the sensory cell area. The apparatus comprises a signal processor for producing a bias signal and an input device for inputting the bias signal to a sensory cell area associated with a sensory cell whose function is to be enhanced. Inputting the bias signal to a sensory cell area effectively lowers the threshold of sensory cells with which the sensory cell area is associated.

I claim:

1. A method for enhancing the ability of a threshold-based sensory cell to respond to a subthreshold stimulus comprising the steps of:

a) locating an area of the body associated with a sensory cell area;
b) generating a bias signal; and,
c) inputting the bias signal to the located area wherein the bias signal causes the **threshold of sensory cells in the sensory cell area to be exceeded in response to the subthreshold stimulus thereby effectively lowering the threshold of the sensory cells in the sensory cell area,** wherein the step of generating a bias signal further comprises the step of transducing the subthreshold stimulus to the sensory cell area into an *electrical signal* and generating the bias signal in response to the *electrical signal.*

2. The method of claim 1 wherein the located area comprises a nerve.

3. The method of claim 1 wherein the located area comprises the sensory cell area.

4. The method of claim 1 wherein the located area comprises a muscle.

5. The method of claim 1 wherein the bias signal comprises a noise signal.

6. The method of claim 1 further comprising: sensing said subthreshold stimulus; wherein **the bias signal comprises an electrical signal which is modulated in response to the sensed subthreshold stimulus.**

7. The method of claim 1 wherein the bias signal comprises a periodic signal.

8. The method of claim 1 wherein the bias signal comprises a high frequency deterministic signal.

9. The method of claim 1 wherein the bias signal comprises a magnetic field.

10. The method of claim 9 wherein the magnetic field comprises a randomly fluctuating field intensity.

11. The method of claim 1 wherein the **bias signal comprises a mechanical stimulus.**

12. The method of claim 1 wherein the bias signal comprises a predetermined signal.

13. The method of claim 12 wherein the predetermined signal is calibrated according to a function which the threshold-based sensory cell performs.

14. A method for enhancing the ability of a threshold-based sensory cell to respond to a subthreshold stimulus comprising the steps of:

a) sensing the subthreshold stimulus to a sensory cell area;

b) generating an electrical signal in response to the subthreshold stimulus; and

c) inputting the electrical signal to the sensory cell area wherein the electrical signal causes the threshold of sensory cells in the sensory cell area to be exceeded thereby effectively lowering the threshold of the sensory cells in the sensory cell area.

15. The method of claim 14 further comprising the step of:

d) determining an optimal level for a parameter of the electrical signal, wherein the step of inputting an electrical signal comprises inputting an electrical signal having the parameter with the optimal level.

16. The method of **claim 15** wherein the **parameter comprises frequency.**

17. The method of **claim 15** wherein the **parameter comprises amplitude.**

18. The method of claim 14 wherein the step of generating comprises generating a noise signal in response to the sensed subthreshold stimulus.

19. The method of claim 14 wherein the step of generating comprises generating the electrical signal in response to the subthreshold stimulus, and modulating the electrical signal in response to the sensed subthreshold stimulus.

20. The method of claim 14 wherein the step of inputting comprises locating a sensory nerve associated with the sensory cell area, implanting a nerve cuff around the located sensory nerve and inputting the electrical signal through the implanted nerve cuff.

21. The method of claim 14 wherein the step of inputting comprises locating a sensory nerve associated with the sensory cell area, positioning a surface electrode

on the exterior of the body in an area associated with the sensory cell area and inputting the electrical signal through the surface electrode.

22. The method of claim 14 wherein the step of inputting comprises locating the sensory cell area, implanting electrodes at the sensory cell area and inputting the electrical signal through the implanted electrodes.

23. The method of claim 14 wherein the step of inputting comprises positioning a muscle stimulator in an area around a muscle associated with the sensory cell area and inputting the electrical signal through the muscle stimulator, wherein the muscle stimulator stimulates a muscle thereby stimulating the sensory cell with which the muscle is associated.

24. The method of claim 23 wherein the muscle stimulator mechanically stimulates the muscle.

25. The method of claim 14 wherein the step of inputting comprises positioning a tendon stimulator in an area around a tendon associated with the sensory cell area and inputting the electrical signal through the tendon stimulator, wherein the tendon stimulator stimulates a tendon thereby stimulating the sensory cell with which the tendon is associated.

26. The method of claim 25 wherein the tendon stimulator mechanically stimulates the tendon.

27. The method of claim 14 wherein the sensory cell area comprises at least one sensory neuron.

28. The method of claim 14 wherein the sensory cell area comprises at least one sensory receptor.

29. The method of claim 14 wherein the **sensory cell area is associated with the proprioceptive system**.

30. The method of claim 14 wherein the sensory cell area is associated with the urinary tract.

31. The method of claim 30 wherein the sensory cell area is associated with the bladder.

32. The method of claim 14 wherein the sensory cell area is associated with the circulatory system.

33. The method of claim 32 wherein the sensory cell area is associated with the heart muscle.

34. The method of claim 14 wherein the sensory cell area is associated with the respiratory system.

35. The method of claim 14 wherein the sensory cell area is associated with the auditory system.

36. The method of claim 14 wherein the sensory cell area is associated with the visual system.

37. The method of claim 14 wherein the sensory cell area is associated with the vibration-sensation system.

38. The method of claim 14 wherein the sensory cell area is associated with the temperature-sensation system.

39. The method of claim 14 wherein the **sensory cell area is associated with the touch-pressure sensation system**.

Collins, J. J.(2000) US Patent 6032074: Method and apparatus for improving the function of sensory cells. Trustees of Boston University, Boston, MA, US.

Abstract: A method and system for enhancing the function of sensory cells. The method includes locating a sensory cell area associated with the sensory cell whose function is to be enhanced, and inputting a bias signal to the sensory cell area. The system includes a signal processor for producing a bias signal and an input device for inputting the bias signal to a sensory cell area associated with a sensory cell whose function is to be enhanced. Inputting the bias signal to a sensory cell area effectively lowers the threshold of sensory cells with which the sensory cell area is associated.

I claim:

1. A system for effectively lowering the threshold of a nervous system sensory cell, comprising:
   - a signal processor for producing at least one bias signal;
   - input means for inputting said at least one bias signal to a sensory cell area associated with the sensory cell, wherein said signal processor produces at least one bias signal causes the threshold of sensory cells to an externally applied signal in the sensory cell area to be exceeded thereby effectively lowering the threshold of said sensory cells; and
   - a controller for controlling the signal processor and input means.
2. The system of claim 1 further comprising a transducer coupled to said controller for transducing an input stimulus to the sensory cell area into an electrical signal.
3. The system of claim 1, wherein the controller controls the transducer, signal processor and input means.
4. The system of claim 3 wherein the **controller modulates each bias signal**.
5. The system of claim 1 wherein each bias signal is a non-modulated signal.
6. The system of claim 1 wherein the **input means comprises a distributed array of input devices**.
7. The system of claim 1 wherein the signal processor further comprises calibration means for determining an optimal level for a parameter of the bias signal.
8. The system of claim 7 wherein the **parameter comprises frequency**.
9. The system of claim 7 wherein the **parameter comprises amplitude**.
10. The system of claim 1 wherein the input means comprises at least one nerve cuff.
11. The system of claim 1 wherein the input means comprises at least one magnetic field stimulator.
12. The system of claim 1 wherein the input means comprises electrodes.
13. The system of claim 1 wherein the input means comprises at least one muscle stimulator, wherein each muscle stimulator stimulates a muscle thereby stimulating a sensory cell area with which the muscle is associated.

14. The system of claim 1 wherein the input means comprises a tendon stimulator, wherein each tendon stimulator stimulates a tendon thereby stimulating a sensory cell area with which the tendon is associated.

McTeigue, M. H. and A. Zias (1993) U.S. Patent 5221088: Sports training system and method, U. S.

A sports training aid has a pair of foot sensors, insertable in a pair of shoes, which generate measurement signals indicative of weight applied to each of the foot sensors. The training aid compares the measurement signals with a specified range of values and produces audible sounds indicative of the relationship between those measurement signals and the specified range of values, thereby providing the training aid's user with immediate audible feedback regarding weight shifts. A grip sensing version of the sports training aid uses a grip pressure sensor which generates a measurement signal indicative of grip pressure applied to the handle of a swingable object, such as a golf club or baseball bat. When the user's grip pressure falls outside specified threshold values, audible tones are generated. In both versions, the user receives the audible feedback signals via a headset worn while using the sports training aid. A spinal tilt version is used to train a person to maintain proper spinal tilt during a sports motion, and a shoulder rotation is used to train a person to achieve a proper degree of shoulder rotation during a sports motion such as the golf backswing. In each version, the sensor(s) include a transmitter which transmits the measurement signals at a predefined frequency. The transmitted measurement signals are received by a comparator which compares the received signals with the specified range of values. As a result, the sensors and comparator need not be physically connected.

What is claimed is:

1. A sports training apparatus, comprising:

- **sensing means, to which at least a portion of a user's weight is applied, for immediately generating measurement signals indicative of the amount of the user's weight applied to the sensing means;** and
- signaling means for immediately receiving the measurement signals, for immediately comparing the measurement signals with a preselected and adjustable range of criteria, said range of criteria being set to selected percentages of a fixed quantity, said fixed quantity being determined solely by the user's total weight, and **for immediately providing to the user sensory signals which undergo a distinct change when the measurement signal crosses a limit of the range and which thus immediately inform the user whether the amount of the user's weight applied to the sensing means is within a preselected range.**

2. The sports training apparatus of claim 1,

- further including calibration means for registering a signal corresponding to the user's total weight, and for setting said preselected and adjustable range to selected percentages of the user's total weight.

3. The sports training apparatus of claim 1, wherein said sensory signals are audio signals audible by the user.

4. The sports training apparatus of claim 1 wherein the **sensing means forms part of a shoe insert shaped for insertion into a user's shoe.**
5. The sports training apparatus of claim 4 wherein the sensing means is located so that it senses the weight borne by at least a portion of the ball of the user's foot.
6. The sports training apparatus of claim 4 wherein the sensing means is located so that it senses the weight borne by the heel of the user's foot.
7. The sports training apparatus of claim 4 wherein there are two sensing means which form part of a single shoe insert shaped for insertion into a user's shoe, said two sensing means being positioned beneath different zones of the user's foot.
8. The sports training apparatus of claim 7 wherein one of the sensing means senses the weight borne by at least a portion of the ball of the user's foot and the other sensing means senses the weight borne by at least a portion of the heel of the user's foot.
9. The sports training apparatus of claim 1 wherein the preselected range can be adjusted so that it has a lower limit but no upper limit.
10. The sports training apparatus of claim 1 wherein the preselected range can be adjusted so that it has an upper limit but no lower limit.
11. The sports training apparatus of claim 1 wherein the preselected range can be adjusted so that it has a lower limit and an upper limit, and wherein the sensory signal is an audible signal which has a first tone when the weight applied to the sensing means results in a measurement signal which is less than the preselected range, and which has a second tone when the weight applied to the sensing means results in a measurement signal which is greater than the preselected range.
12. The sports training apparatus of claim 1 which further comprises a wireless transmitter adjacent to the sensing means for sending the measurement signals to the signaling means, and a receiver adjacent to the signaling means for receiving the measurement signals.
13. The sports training apparatus of claim 1, the signaling means simultaneously providing said sensory signals to the user and to a second person.
14. The sports training apparatus of claim 1 which further comprises
    - a start means which activates the apparatus, and
    - a delay means which delays the provision of said sensory signals to the user for a predetermined delay period after the apparatus has been activated by the start means.
15. A sports training apparatus comprising:
    - sensing means comprising first and second weight sensors to which at least a portion of a user's weight is applied, for immediately generating distinct measurement signals indicative of the amount of the user's weight applied to **each of said weight sensors**; and
    - signaling means for immediately receiving said distinct measurement signals, for immediately comparing the amount of the user's weight applied to each of said first and second weight sensors with first and second predetermined criteria, and for immediately providing to the user distinct first and second sensory signals corresponding to said first and second weight sensors

respectively; said sensor signals changing as the amount of the user's weight applied to each of said first and second weight sensors changes;

- said first sensor signal including an audio signal of a first tonal frequency which denotes a predefined relationship between weight applied to the first weight sensor and said first predetermined criteria, and said second sensor signal including a second tonal frequency which denotes a second predefined relationship between weight applied to the second weight sensor and said second predetermined criteria;
- **whereby the user receives immediate sensory feedback regarding placement of the user's weight.**

16. The sports training apparatus of claim 15, said first and second weight sensors forming part of two shoe inserts shaped for insertion into a user's left and right shoes, each insert including a weight sensor.
17. The sports training apparatus of claim 15, said signaling means simultaneously providing said sensory signals to the user and to a second person.
18. The sports training apparatus of claim 15 each of said first and second sensory signals being an audio signal having a tonal frequency which is related to the amount by which the user's weight applied to the respective weight sensor differs from a preselected value.
19. The sports training apparatus of claim 15 wherein the signaling means compares each of the distinct measurement signals with a respective preselected and adjustable range of criteria, and provides to the user distinct audio signals which undergo a distinct change when the measurement signal crosses a limit of the respective range, and which thus immediately inform the user whether the amount of the user's weight applied to the respective sensing means is within a preselected range.
20. The sports training apparatus of claim 19 wherein the first sensory signal is an audio signal directed to one of the user's ears and the second sensory signal is an audio signal directed to the other one of the user's ears.
21. The sports training apparatus of claim 15 which further comprises
    - a start means which activates the apparatus, and
    - a delay means which delays the provision of said sensory signals to the user for a predetermined delay period after the apparatus has been activated by the start means.
22. A sports training apparatus, comprising:
    - a pair of weight sensors, insertable in a pair of shoes, which immediately generate measurement signals indicative of weight applied to each of said weight sensors;
    - a calibration means for denoting a range of weight values;
    - a speaker for generating audible sounds; and
    - comparator means coupled to said pair of weight sensors, said calibration means and said speaker, for immediately comparing said measurement signals with said range of weight values and for immediately sending audio control signals to said speaker so as to immediately produce audible sounds indicative of the relationship between said measurement signals and said range of weight values;

- said comparator means sending audio control signals so as to produce distinct audible sounds for each said weight sensor indicative of whether weight applied to each weight sensor is within said range of weight values;
- whereby a user of said sports training apparatus receives immediate audible feedback regarding the user's weight distribution.

23. The sports training apparatus of claim 22, wherein
    - said speaker comprises a pair of headphones; and
    - said comparator sends audio control signals to each one of said pair of headphones indicative of whether weight applied to a corresponding one of said weight sensors is within said range of weight values.
24. The sports training apparatus of claim 22,
    - said sports training apparatus including wireless transmitters and a receiver for sending measurement signals from said weight sensors to said comparator means;
    - whereby said weight sensors and comparator means need not be physically connected.
25. A sports training apparatus, comprising:
    - a grip pressure sensor which immediately generates measurement signals indicative of grip pressure applied to the handle of a swingable object;
    - signaling means for immediately receiving said measurement signals generated by said grip pressure sensor, for immediately comparing the user's grip pressure with predetermined criteria comprising a preselected value, and for immediately providing corresponding sensory signals to the user; said sensory signals changing as the user's grip pressure changes; and
    - calibrations means for recording a signal indicative of the user's maximum grip pressure, for selecting a percentage value thereof, and for setting said preselected value to said selected percentage of the user's maximum grip pressure;
    - whereby the user receives immediate sensory feedback regarding the user's grip pressure.

26. The sports training apparatus of claim 25, wherein said predetermined criteria comprises a range of values surrounding a specified value.
27. The sports training apparatus of claim 25, wherein said predetermined criteria are adjustable to match said user's skill.
28. The sports training apparatus of claim 25, wherein said sensory signal is an audio signal audible by the user.
29. The sports training apparatus of claim 25 wherein the comparator compares the user's grip pressure with a preselected and adjustable range of criteria and provides to the user sensory signals which undergo a distinct change when the user's grip pressure crosses a limit of the preselected range.
30. The sports training apparatus of claim 25 which further comprises
    - a start means which activates the apparatus, and
    - a delay means which delays the provision of said sensory signals to the user for a predetermined delay period after the apparatus has been activated by the start means.

31. The sports training apparatus of claim 25, said signaling means simultaneously providing said sensory signals to the user and to a second person.
32. A sports training apparatus, comprising:
    - a grip pressure sensor which immediately generates a measurement signal indicative of grip pressure applied to the handle of a swingable object;
    - calibration means for denoting a range of pressure values;
    - a speaker for generating audible sounds; and
    - comparator means coupled to said pressure sensor, said calibration means and said speaker, for immediately comparing said measurement signal with said range of pressure values and for immediately sending audio control signals to said speaker so as to immediately produce audible sounds indicative of the relationship between said measurement signal and said range of pressure values;
    - whereby a person using said sports training apparatus receives immediate audible feedback regarding maintenance of grip pressure within said range of pressure values.
33. The sports training apparatus of claim 32, wherein said speaker comprises at least one headphone.
34. The sports training apparatus of claim 32,
    - said sports training apparatus including wireless transmitters and a receiver for sending measurement signals from said grip pressure sensor to said comparator;
    - whereby said grip pressure sensor and comparator need not be physically connected.
35. A sports training apparatus, comprising:
    - a plurality of sensing means, said plurality of sensing means including first and second weight sensors and a grip pressure sensor;
    - mode selection means for selecting one of a plurality of predefined training modes, each training mode using specified ones of said plurality of sensing means; and
    - signaling means, coupled to said mode selection means, for immediately receiving said signals generated by said ones of said sensing means corresponding to said selected training mode, for immediately comparing the received signals with predetermined criteria, and for immediately providing corresponding sensory signals to the user;
    - when a first one of said training modes is selected, said signaling means comparing the amount of the user's weight applied to each of said first and second sensors with said predetermined criteria, and providing distinct first and second corresponding sensory signals to the user; and
    - when a second one of said training modes is selected, said signaling means comparing the user's grip pressure with predetermined criteria, and providing corresponding sensory signals to the user;
    - whereby the user receives immediate sensory feedback from the specified ones of said plurality of sensing means.

36. The sports training apparatus of claim 35, wherein said predetermined criteria in at least one of said training modes comprises a range of values surrounding a specified value.
37. The sports training apparatus of claim 35, wherein said predetermined criteria in at least one of said training modes comprises a preselected value;
   - said apparatus further including calibration means for recording a signal indicative of the user's total weight, for selecting a percentage value, and for setting said preselected value to said selected percentage of the user's total weight.
38. The sports training apparatus of claim 35, wherein said predetermined criteria are adjustable to match said user's skill.
39. The sports training apparatus of claim 35, wherein said sensory signal is an audio signal audible by the user.
40. The sports training apparatus of claim 35 which further comprises
   - a start means which activates the apparatus, and
   - a delay means which delays the provision of said sensory signals to the user for a predetermined delay period after the apparatus has been activated by the start means.
41. The sports training apparatus of claim 35, said signaling means simultaneously providing said sensory signals to the user and to a second person.
42. A method of training a person to distribute and shift the person's weight in accordance with a prescribed weight distribution pattern, the steps of the method comprising:
   - placing independent weight sensing means beneath each of the person's two feet;
   - sensing the weight borne by each of said independent sensing means;
   - comparing the weight borne on a first one of said independent sensing means with a first prescribed value, and providing a first corresponding sensory feedback signal to the person; and
   - comparing the weight borne on the other one of said independent sensing means with a second prescribed value, and providing a second corresponding sensory feedback signal to the person;
   - said first and second sensory signals including an audio signal of a first tonal frequency which denotes a predefined relationship between weight borne by the person's first foot and said first prescribed value, and an audio signal of a second tonal frequency which denotes a predefined relationship between weight borne by the person's other foot and said second prescribed value.
43. The training method of claim 42, wherein said first sensory signal is an audio signal directed to one of the user's ears and said second sensory signal is an audio signal directed to the other one of the user's ears.
44. The training method of claim 42, further including:
   - simultaneously providing said sensory signals to the person whose weight is being sensed and to a second person.

45. The training method of claim 42, including providing audio signals each having a tonal frequency which is related to the amount by which the person's weight borne by a corresponding foot differs from a preselected value.
46. A method of training a person to maintain proper grip pressure on a swingable object, the steps of the method comprising:
- positioning a grip pressure sensor between at least one of the person's hands and a swingable object;
- calibrating a prescribed value by registering a signal indicative of the person's maximum grip pressure;
- selecting a percentage value of the person's maximum grip pressure;
- sensing the person's grip pressure on the swingable object;
- comparing said grip pressure with the selected percentage value of the person's maximum grip pressure; and
- providing a corresponding sensory feedback signal to the person.

47. A method of training a golfer to distribute the golfer's weight in accordance with a prescribed weight distribution pattern, the steps of the method comprising:
- placing weight sensing means beneath one of the golfer's feet;
- sensing the weight borne by said one of the golfer's feet;
- comparing the weight borne by said one of the golfer's feet with a preselected and adjustable range of criteria, said range of criteria being set to selected percentages of a fixed quantity, said fixed quantity being determined solely by the user's total weight; and
- immediately providing to the golfer sensory signals which undergo a distinct change when the weight borne by said one of the golfer's feet crosses a limit of said preselected range.

48. The method of claim 47 wherein there is a single weight sensing means which is placed under one of the golfer's feet.
49. The method of claim 48 wherein the single weight sensing means is placed under the golfer's left foot.
50. The method of claim 48 wherein the single weight sensing means is placed under the golfer's right foot.
51. The method of claim 47 wherein there are two weight sensing means, one of which is placed under the ball of one of the golfer's feet and the other of which is placed under the heel of said one of the golfer's feet.
52. The method of claim 51 wherein the two weight sensing means are placed under the golfer's left foot.
53. A method of training a person to maintain proper grip pressure on a swingable object, the steps of the method comprising:
- positioning a grip pressure sensor between at least one of the person's hands and the swingable object;
- continuously generating measurement signals indicative of the person's grip pressure on the swingable object;
- continuously and immediately comparing the person's grip pressure with a preselected and adjustable range of criteria; and

- providing to the person sensor signal which undergo an immediate and distinct change when the person's grip pressure crosses a limit of said preselected range.

54. A method according to claim 53 wherein a golfer is trained to maintain proper grip pressure on a golf club.
55. A sports training apparatus comprising:
    - sensing means comprising first and second weight sensors to which at least a portion of a user's weight is applied, for immediately generating distinct measurement signals indicative of the amount of the user's weight applied to each of said weight sensors; and
    - signaling means for immediately receiving said distinct measurement signals, for immediately comparing the amount of the user's weight applied to each of said first and second weight sensors with first and second predetermined criteria, and for immediately providing to the user distinct first and second sensory signals corresponding to said first and second weight sensors respectively; said sensor signals changing as the amount of the user's weight applied to each of said first and second weight sensors changes;
    - said first sensory signal being an audio signal directed to one of the user's ears and said second sensory signal being an audio signal directed to the other one of the user's ears;
        - whereby the user receives immediate sensory feedback regarding placement of the user's weight.

Fletcher, J. C. and W. L. Scott (1973) U. S. Patent 3751733: Tactile sensing means for prosthetic limbs.

An improved prosthetic device characterized by a frame including a socket for mounting the frame on the stump of a truncated human appendage and having a plurality of flexible digits extended from the distal end thereof. Within the digits there are transducers, provided as sensing device for detecting tactile stimuli, connected through a power circuit with a slave unit supported by a strap and fixed to the stump, whereby the tactile stimuli detected at the sensing devices are reproduced and applied to the skin of the appendage for thus stimulating sensory organs located therein.

I claim:

1. Tactile Sensing Means for a prosthetic limb of the type including a terminal member having a plurality of digits extending therefrom through which taction is applied and means for mounting the limb on a human appendage comprising:

- a temperature transducer and a pressure transducer supported by said digits for detecting tactile stimuli and providing electrical output signals proportionate to the magnitude of said stimuli;
- a pair of opposed solenoids electrically coupled with said pressure transducer;
- a resistance heater electrically coupled with said temperature transducer;
- strap means for mounting said solenoids and said heater on said appendage in contiguous engagement therewith with the armatures of said solenoids disposed on opposite sides of said appendage whereby as taction is applied to

said digits, tactile stimuli are detected by said sensing means and communicated to said appendage proportionate to the magnitude of said stimuli, with said armatures when energized applying pressure to the flesh of said appendage and said heater applying heat to said appendage.

Zhu, H. S., G. F. Harris, J. J. Wertsch, W. J. Tompkins and J. G. Webster (1991) A microprocessor-based data-acquisition system for measuring plantar pressures from ambulatory subjects. *IEEE Trans Biomed Eng* 38(7):710-4.

- Describes portable plantar pressure acquisition system
- "future applications include sensory substitution for insensate feet . . ."
- Detailed graphic with electrotactile array on back- no description
- one feedback stimulator per insole sensor (7 per foot)

Wertsch, J. J., J. G. Webster and W. J. Tompkins (1992) A portable insole plantar pressure measurement system. *J Rehabil Res Dev* 29(1):13-8.

- Same diagram, no description
- Wertsch has a patent on a particular Foot Force Sensor (US 5408873) which does not claim feedback.

PROBLEM SOLVED

The device disclosed here improves the balance control of patients suffering from reduced peripheral sensation. This improvement is expected to lead to a reduced risk of falling, thereby reducing the probability of serious injury. In addition, the proposed device is expected to mitigate the postural deficits resulting from long-term exposure to reduced pressure on the foot sole, such as those experienced after prolonged bedrest or microgravity exposure.

POSSIBLE USES FOR THE INVENTION

The disclosed device is expected to be used for a number of purposes:

1. As a balance aid for patients suffering from peripheral sensory neuropathies.
2. As a countermeaure to reduce plantar sole hypersensitivity resulting from prolonged bedrest, reduced weight bearing, or microgravity exposure.
3. As a means to produce artificial sensations of pressure under the feet, such as might be desired in a virtual environment.

DISADVANTAGES OR LIMITATIONS

1. The balance control system utilizes feedback from the vestibular, visual, proprioceptive, and somatosensory systems to control balance. The balance system is therefore highly redundant, and can operate without one or more of these senses. The effect of reduced plantar sensation on balance control is expected to be mitigated by compensatory increases in the importance of other sensory systems. Nevertheless, studies have strongly suggested that reduced plantar sensation is associated with what appear to be permanent decrements in balance control. In addition, the reductions in plantar sensation are commonly concurrent with reductions in proprioception, visual

acuity, and motor function. For these patients, the replacement of lost plantar sensation may greatly improve to their ability to perform activities involving ambulation.

2. It is expected that the integration of the feedback provided by this device into automatic postural responses will require a training. The inventors have, however, demonstrated significant improvements in the control of quiet stance by healthy subjects wearing a prototype device after only a few minutes of training. While these results could be due in part to cognitive responses to the feedback , there is further evidence in the literature that suggests that biofeedback can be integrated into automatic responses given a more substantial training period[10].
3. Peripheral neuropathies are typically progressive in nature. While feedback could be mounted on the lower leg of a subject showing early signs of sensory neuropathy, their dysfunction would eventually spread to the lower leg as well. The feedback array must then be moved proximally with the advance of disease. Further progression of disease would likely result in decrements in muscle function that cannot be compensated for by this device.
4. Other parties may be working on similar devices. In particular, an email posted to the BIOMCH-L Biomechanics Email List on 2/6/2000 indicated that three undergraduate engineering students at Washington University (St. Louis, MI) had just begun a similar project as part of a senior design project. No further information regarding their work has been obtained. In addition, Charles Layne at the University of Houston has done work involving vibration of the foot sole and may be working toward a portable device. He has also been involved in the design and testing of a pressure boot for use in microgravity.

STATE OF DEVELOPMENT

A prototype device has been developed at the NeuroMuscular Research Center. It consists of:

1. (2) arrays of 7 Force-Sensing Resistors (FSR's), one for each foot sole
2. A FSR Amplifier Unit
3. A microcomputer-controlled Data Acquisition Processor (DAP)
4. A Feedback Amplifier Unit
5. (2) arrays of 4 vibrators for each leg.

In the current implementation, normal pressure information from each FSR obtained through the FSR Amplifier Unit. These signals are acquired by the DAP and used to estimate the location of the Center-of-Pressure under each foot in real time. A computer algorithm uses this information to select and modulate the frequency of the appropriate vibrator on the ipsilateral limb. The feedback signals are sent to the vibrators via the Feedback Amplifier Unit, producing localized vibration of the skin on the leg.

A study of the effect of the prototype device on the posture control on 10 healthy adults was performed. In this study, feedback was provided on only one leg in order to simplify its use. Subjects were asked to stand as still as possible after a few minutes of training with the device. Using standard quantitative techniques for the analysis of posture, we

showed that the use of the device caused a significant reduction in low frequency sway, which can be interpreted as "tighter" control. These results were reported as a Biomedical Engineering Undergraduate Senior Project, although details regarding the device that were considered proprietary were not presented to the public.

Further study is needed to quantify the amount of training needed before feedback from the device can be integrated into unconscious postural responses. Initial tests of simulated slips while wearing the device suggest that the device does not delay the postural responses, as might be expected with the introduction of noise. In order to see decreases in the latency of slip responses, we expect that subjects will require significant training. The development of a portable version of the device will allow prolonged training by either healthy subjects or neuropathic patients, as well as enable an investigation of its effect on gait.

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Docket No. BU5901

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

Exhibit E

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)

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COPY

__ Additional inventors are being named on the ____ separately numbered sheets attached hereto.

TITLE OF THE INVENTION (280 characters max)

SENSORY PROSTHETIC FOR IMPROVED BALANCE CONTROL

CORRESPONDENCE ADDRESS

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____ Customer Number

Type Customer Number here

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ENCLOSED APPLICATION PARTS ***(check all that apply)***

X Specification and Drawings *Number of Pages* 18

X Coversheet (1 page)

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

X A check or money order is enclosed to cover the filing fees.

____ No fee is to be paid at this time.

____ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Order Account Number: 19-0079

FILING FEE AMOUNT $ 75.00

X **APPLICATION ENTITLED SMALL ENTITY STATUS**

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

____ No.

____ Yes, the name of the U.S. Government agency and the Government contract number are: ________

CERTIFICATION UNDER 37 C.F.R 1.10

I hereby certify that this correspondence and the documents referred to as attached therein are being deposited with the United States Postal Service on January 5, 2001 in an envelope as "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10, Mailing Label Number EL604780833US addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Deborah M. Costello

Signature

Deborah M. Costello

Type or print name of person certifying

Respectfully submitted,

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

Docket No.BU.5901

COPY

UNITED STATES PROVISIONAL PATENT APPLICATION

of

LARS I.E. ODDSSON

and

PETER F. MEYER

for

SENSORY PROSTHETIC FOR IMPROVED BALANCE CONTROL

INTRODUCTION

A portable feedback device is disclosed which measures information related to the balance of a person while walking or standing and produces a stimulation of the skin that encodes that information. The device could be used to improve balance in patients suffering from deficits in foot sole cutaneous sensation or to produce an artificial feeling of pressure under the feet for integration into virtual environments. In addition, the device could be used to provide cutaneous foot sole stimulation to bedridden patients or astronauts in a microgravity environment, thereby reducing balance deficits related to long-term adaptation to these conditions.

GENERAL PURPOSE

It has been estimated that as high as 20% of the elderly population in the United States may be suffering from peripheral neuropathies, largely as a consequence of diabetes [13]. Peripheral neuropathic patients exhibit increased body sway during quiet standing [2]. Peripheral neuropathies have been associated with increased thresholds for the perception of ankle inversion/eversion [14] and a reduced ability to maintain a unipedal stance [11], suggesting a reduction in balance control while walking. Epidemiological evidence has linked peripheral neuropathies with an increased risk of falling [12, 13]. Postural responses to floor perturbations in peripheral (diabetic) neuropathy patients are delayed and are poorly scaled to the perturbation amplitude [4].

The most common symptom of peripheral neuropathies is a reduction in sensation from the soles of the feet. A number of studies have provided evidence that afferent information from the feet is an important part of the balance control system [1, 3, 5, 6, 8, 9]. A recent study on adaptation to microgravity suggests that foot sole pressure may be critical for triggering the anticipatory postural adjustments that are normally required to maintain balance during arm movements [7]. An investigation is currently underway at the NeuroMuscular Research Center to quantify the specific role played by foot sole cutaneous afferents in balance control under both static and dynamic conditions.

The device disclosed here is a sensory substitution system that provides information regarding foot sole pressure distribution to patients who are no longer able to acquire this information by natural means. A patient wearing this device will achieve improved upright balance control, reducing their risk of falls and associated injuries. With practice, this information will be integrated into the patients unconscious postural control system and no longer require conscious effort.

DESCRIPTION OF THE DEVICE

The preferred embodiment of the device consists of three parts:

a) An array of sensors arranged under the soles of each foot which transduce the magnitude of pressure exerted on the foot sole at each sensor location.

b) A signal processor that converts the signal obtained from each pressure transducer into estimates of the location and magnitude of the resultant ground reaction force exerted on each foot (center-of-pressure, or COP). The signal processor then encodes the estimate of COP into signals that drive elements of the stimulator array.
c) An array of vibrotactile stimulators that are placed upon the leg in a plane approximately parallel to the plane of the foot sole in four locations on each leg: anterior, posterior, medial, & lateral. In response to signals produced by the signal processor, the array provides vibrotactile stimulation of the skin of the leg.

A simple diagram of the preferred embodiment is attached.

Using this portable, wearable device, the subject receives cutaneous stimulation on the leg regarding the location and magnitude of the ground reaction force under the ipsilateral foot. With training, a patient suffering from reduced plantar sensation will learn to make postural corrections in response to this stimulation in the same manner as a healthy person would react to changes in the pressure distribution under their feet.

ADVANTAGES AND IMPROVEMENTS OVER EXISTING DEVICES

To our knowledge, there are no commercially available sensory substitution devices designed to improve postural balance. The device disclosed here is similar to the device described in US Patent 4760850 (expired; see below). It possesses a number of advantages over US4760850, including:

a) The simplification of the feedback such that it can more easily be integrated into the unconscious postural control system. The reduction of individual pressure signals to an estimate of COP position and magnitude under each foot is easier to integrate into the postural control system than information regarding a number of separate pressure transducers.
b) The coding of information using frequency modulation rather than amplitude modulation. Cutaneous stimulation has been shown to excite cutaneous mechanoreceptors on a 1 to 1 basis for a wide range of input frequencies. As a result, some cutaneous mechanoreceptors will respond to an artificial stimulation (vibrotactile or electrotactile) in the same manner as they would respond to a pressure stimulus. Simulating a natural pressure stimulus with an artificial one in this manner should facilitate the integration of this information into the unconscious balance control system.
c) The location of feedback on the legs and oriented in a plane parallel to the plane of the foot sole should facilitate the integration of feedback information into the unconscious balance control system.
d) The explicit purpose of this device is for improved balance control in patients suffering from reduced foot sensation. The claims in US4760850 only refer to use by patients with injured spinal cords. While not mutually exclusive, the target population for this work is significantly larger than that described by the previous patent.

U.S. Patent 5878378 describes a training device integrated into a ski boot that provides a signal to the wearer that the pressure difference between force sensing resistors under the

forefoot and rearfoot has exceeded a threshold value. The device disclosed here has a number of advantages over this device:

a) The previous device only communicates to the wearer whether or not the fore-aft pressure distribution exceeds a threshold. The current device provides feedback regarding both the magnitude of this pressure difference and the magnitude of the total pressure under each foot.
b) Feedback is provided in the medial-lateral direction as well as the anterior-posterior direction.
c) The previous device was intended for training purposes only. The current device is intended to be worn as a prosthetic for continuous everyday use.

U.S. Patent 5919149 describes a device mounted on the torso that senses body lean and provides feedback to the user regarding body angle, angular velocity, or angular acceleration. In contrast, one variation of the disclosed device includes a transducer that senses and provides feedback regarding the angle and/or angular velocity of the ankle joint only. It is important to note that the angle of body "lean" and the angle between the foot and the shank are very different.

U.S. Patent 5221088 describes a sports training device that provides auditory feedback regarding the distribution of body weight between the feet or between two sites under each foot. The device disclosed here embodies a number of improvements:

a) US5221088 is specifically intended for training purposes. The device disclosed here is intended to be used as a balance aid for use during activities of daily living.
b) US5221088 describes the use of auditory cues to give information regarding weight distribution to the wearer. These cues can be expected to be distracting and interfere with the normal hearing of the wearer. The preferred embodiment of the device disclosed here uses feedback on the skin of the leg, a sensory area that is not normally used for other activities.
c) US5221088 provides no information regarding the medial/lateral distribution of body weight under each foot. This information may be very important to balance control while walking.
d) US5221088 describes a feedback signal that changes as the sensor signal reaches a threshold. In the device disclosed here, the feedback stimulus is a continuous function of the sensor signal, providing much greater resolution.

U.S. Patent 3751733 describes a means to transduce pressure and/or temperature from a prosthetic limb and provide feedback to the limb stump. An alternative embodiment of the device disclosed here has an advantage over US3751733 in that the feedback provided represents the Center-of-Pressure under a prosthetic foot, rather than the pressure at one or more location. This reduction of information may be crucial to the integration of feedback into the unconscious balance control system.

POSSIBLE VARIATIONS AND MODIFICATIONS

1. The sensor array and/or feedback array are incorporated into a stocking, shoe, or boot.

2. The device acquires, encodes, and provides feedback regarding shear forces under the foot.
3. The device acquires, encodes, and provides feedback regarding angle and or angular velocity of the lower leg with respect to the foot.
4. The device stimulates the cutaneous foot sole for the purpose of reducing postural deficits associated with long-term exposure to reduced foot loads, such as those incurred by bedridden patients on earth or astronauts in microgravity.
5. The device stimulates the cutaneous foot sole for the purpose of producing an artificial feeling of pressure or shear force, such as might be used in virtual environments.
6. The device stimulates the skin of a part of the body other than the foot sole for the purpose of producing an artificial feeling of pressure or shear force, such as might be used in virtual environments.
7. The device stimulates the cutaneous foot sole in response to pressure under the foot for the purpose of amplifying the sensation of pressure.
8. The implementation of a signal processing method such that a range of COP positions and/or magnitudes produce no output from the feedback array (i.e. sensory "dead zone").
9. The mode of feedback is tactile, vibrotactile, electrotactile, visual, thermal, and/or auditory.
10. The sensor array is implanted into or under the skin or within the body.
11. The feedback array is implanted into or under the skin or within the body.
12. The feedback array is implanted such that the feedback elements are adjacent to or in contact with one or more sensory neurons or sensory nerves.
13. The sensor array is affixed to or embedded within a prosthetic limb.
14. The connection between any or all of the device components is wireless.
15. The sensor signals and/or feedback signals are monitored remotely or recorded for the purpose of evaluating the effect or function of the device.

FEATURES BELIEVED TO BE NEW

1. Conversion of pressure information from multiple sensors located on the foot sole to a single measure of Center-of-Pressure. This simplified feedback should be more easily integrated into the balance control system than feedback encoding the pressure distribution directly.
2. Feedback of location of center-of-pressure under each foot in both anterior/posterior and medial/lateral directions. Sensation of medial-lateral direction may be particularly important for balance control during walking, which involves repeated periods of unipedal stance.
3. Location of feedback stimulators on the legs, arranged in a plane parallel to that of the foot sole. This may facilitate sensory integration into normal balance control.
4. Encoding of postural information by means of modulating the frequency of electrotactile or vibrotactile stimulators within a feedback stimulation array. This type of stimulation will more closely approximate the normal sensation of pressure, since greater amplitudes of pressure on the skin normally result in greater firing frequency in cutaneous mechanoreceptors.

5. Implementation of a feedback system that incorporates a range of input stimuli that produce no output to the feedback array (sensory dead-zone). This is based upon the theory that normal posture control may involve mechanisms that are insensitive to sensory feedback as well as those that rely on sensory feedback. This claim could potentially conflict with Claim 1 of U. S. Patent 5878378.
6. The variation that includes the acquisition of foot-sole shear force information and feedback of this information to the wearer (tactile, electrotactile, vibrotactile, visual, thermal, or auditory feedback). This feedback would provide information regarding the stretch of the foot sole skin and be used to sense slipping of the foot with respect to the support surface.
7. The variation that includes one or more modes of feedback (tactile, vibrotactile, electrotactile, visual, thermal, auditory).
8. The variation that includes acquisition of ankle angle information (plantar/dorsiflexion and/or inversion/ eversion) and feedback of this information to the wearer using electrotactile, vibrotactile, visual, thermal, or auditory feedback.
9. The variation that includes the acquisition of shear force information from the foot sole and feedback of this information to the wearer using electrotactile, vibrotactile, visual, thermal, or auditory feedback.
10. The variation that includes the integration of information regarding the location of center-of-pressure, total limb load, ankle angle, and/or shear force under each foot into signals that drive the feedback array.
11. The variation that includes the location of vibrotactile or electrotactile feedback stimulators on the soles of the feet to produce an effective amplification of sensation from the cutaneous foot sole. Such a system might compensate for reduced plantar sensation without requiring stimulation of a skin area that is not normally involved in balance control. In addition, such a system might be useful in a microgravity environment. Foot sole pressure sensors appear to be important to the triggering of normal anticipatory postural responses that precede activities that perturb the center of mass, such as arm raises. By amplifying the sensation of pressure under the feet, these anticipatory responses may be triggered even in a microgravity environment. While such responses may be unnecessary in microgravity, maintaining these reflexes throughout space flight may accelerate the re-adaptation to terrestrial gravity upon return to earth. This claim is similar to, but does not conflict with Claims 4, 6, 8, & 9 of BU held U.S. Patent 6032074 and Claims 1c, 6, 11, 16, & 17 of BU held U.S. Patent 5782873. These previous patents described the reduction of sensory thresholds by the introduction of a bias signal. In the current device option, sensation is improved by the amplification of the pressure stimulus to the foot while the foot sole cutaneous mechanoreceptor sensory thresholds remain the same.
12. The variation that includes the location of vibrotactile or electrotactile feedback stimulators on the soles of the feet to stimulate the cutaneous sensory receptors of the foot sole. This "exercise" of foot sole sensation may reduce the hypersensitivity of the foot sole normally seen after prolonged periods of reduced weight bearing and improve balance control following a return to normal weight bearing.
13. The variation that includes the stimulation of the cutaneous foot sole in order to provide a false feeling of pressure or movement under the feet. This stimulation

would evoke automatic postural responses which would be useful in establishing a feeling of "presence" in a virtual environment.

14. The variation that includes the cutaneous stimulation of parts of the body other than the foot sole, such as the buttocks or back, in order to simulate changes in pressure applied to that area. This stimulation would evoke automatic postural responses which would be useful in establishing a feeling of "presence" in a virtual environment. This variation would be particularly when the subject is sitting within a virtual environment, such as in flight simulator. In this case, cutaneous stimulation may reduce the physical movements of a simulator required to produce a desired sensation.
15. The variation in which the sensor array and/or feedback array are implanted under the skin or within the body.
16. The variation in which the feedback array elements are implanted within the body adjacent to or in contact with sensory neuron(s) or nerves.
17. The variation in which the sensor array is affixed to or embedded within a prosthetic limb. This would provide sensation of load, pressure distribution, shear force, or "ankle" angle that would not normally be available to the wearer.
18. The variations in which the sensor array, feedback array, or both are implanted under the skin or within the body. This would provide a permanent means of obtaining feedback information no longer available to the patient.

PROBLEM SOLVED

The device disclosed here improves the balance control of patients suffering from reduced peripheral sensation. This improvement is expected to lead to a reduced risk of falling, thereby reducing the probability of serious injury. In addition, the proposed device is expected to mitigate the postural deficits resulting from long-term exposure to reduced pressure on the foot sole, such as those experienced after prolonged bedrest or microgravity exposure.

POSSIBLE USES FOR THE INVENTION

The disclosed device is expected to be used for a number of purposes:

1. As a balance aid for patients suffering from peripheral sensory neuropathies.
2. As a countermeaure to reduce plantar sole hypersensitivity resulting from prolonged bedrest, reduced weight bearing, or microgravity exposure.
3. As a means to produce artificial sensations of pressure under the feet, such as might be desired in a virtual environment.

STATE OF DEVELOPMENT

A prototype device has been developed at the NeuroMuscular Research Center. It consists of:

1. (2) arrays of 7 Force-Sensing Resistors (FSR's), one for each foot sole
2. A FSR Amplifier Unit
3. A microcomputer-controlled Data Acquisition Processor (DAP)

4. A Feedback Amplifier Unit
5. (2) arrays of 4 vibrators for each leg.

In the current implementation, normal pressure information from each FSR obtained through the FSR Amplifier Unit. These signals are acquired by the DAP and used to estimate the location of the Center-of-Pressure under each foot in real time. A computer algorithm uses this information to select and modulate the frequency of the appropriate vibrator on the ipsilateral limb. The feedback signals are sent to the vibrators via the Feedback Amplifier Unit, producing localized vibration of the skin on the leg.

A study of the effect of the prototype device on the posture control on 10 healthy adults was performed. In this study, feedback was provided on only one leg in order to simplify its use. Subjects were asked to stand as still as possible after a few minutes of training with the device. Using standard quantitative techniques for the analysis of posture, we showed that the use of the device caused a significant reduction in low frequency sway, which can be interpreted as "tighter" control. These results were reported as a Biomedical Engineering Undergraduate Senior Project, although details regarding the device that were considered proprietary were not presented to the public.

Further study is needed to quantify the amount of training needed before feedback from the device can be integrated into unconscious postural responses. Initial tests of simulated slips while wearing the device suggest that the device does not delay the postural responses, as might be expected with the introduction of noise. In order to see decreases in the latency of slip responses, we expect that subjects will require significant training. The development of a portable version of the device will allow prolonged training by either healthy subjects or neuropathic patients, as well as enable an investigation of its effect on gait.

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SHORT, NON-CONFIDENTIAL DESCRIPTION OF USEFULNESS

A portable feedback device has been invented which measures information related to the balance of a person while walking or standing and produces a stimulation of the skin which encodes that information. The device could be used to improve balance in patients suffering from deficits in foot sole cutaneous sensation or to produce an artificial feeling of pressure under the feet for integration into virtual environments. In addition, the device could be used to provide cutaneous foot sole stimulation to bedridden patients or astronauts in a microgravity environment, thereby reducing balance deficits related to long-term adaptation to these conditions.

NON-CONFIDENTIAL DESCRIPTION OF USEFULNESS

It has been estimated that as high as 20% of the elderly population in the United States may be suffering from peripheral neuropathies, largely as a consequence of diabetes (1). Peripheral neuropathic patients exhibit increased body sway during quiet standing (2). Peripheral neuropathies have been associated with increased thresholds for the perception of ankle inversion/eversion (3) and a reduced ability to maintain a unipedal stance (4), suggesting a reduction in balance control while walking. Epidemiological evidence has linked peripheral neuropathies with an increased risk of falling (1, 5). Postural responses to floor perturbations in peripheral (diabetic) neuropathy patients are delayed and are poorly scaled to the perturbation amplitude (6).

The most common symptom of peripheral neuropathies is a reduction in sensation from the soles of the feet. A number of studies have provided evidence that afferent information from the feet is an important part of the balance control system (7, 8, 9, 10, 11, 12). A recent study on adaptation to microgravity suggests that foot sole pressure may be critical for triggering the anticipatory postural adjustments that are normally required to maintain balance during arm movements (13). An investigation is currently underway at the NeuroMuscular Research Center to quantify the specific role played by foot sole cutaneous afferents in balance control under both static and dynamic conditions.

A sensory substitution system has been invented which provides information regarding foot sole pressure distribution to patients who are no longer able to acquire this information by natural means. A patient wearing this device will achieve improved upright balance control, reducing their risk of falls and associated injuries. With practice, this information will be integrated into the patients unconscious postural control system and no longer require conscious effort. An alternative embodiment of the device may reduce the balance deficits caused by prolonged exposure to reduced weight bearing, as seen in patients recovering from prolonged bed rest or in astronauts returning to terrestrial gravity. Preventative treatments with this device should reduce the hypersensitivity of the foot soles which contributes to these postural deficits.

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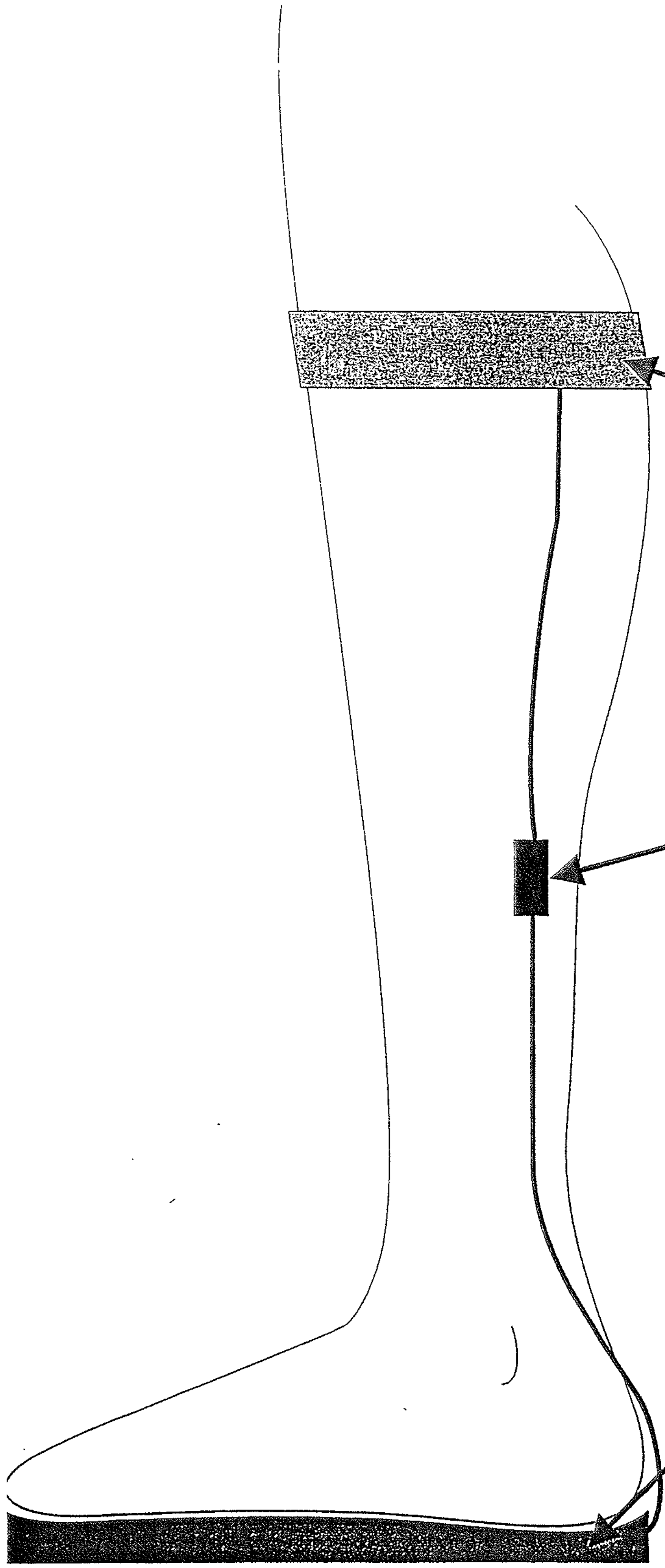
Preferred Embodiment Shown



Uses: Improving static and dynamic balance control, especially in patients suffering from reduced plantar pressure sensation; simulation of balance conditions (Virtual Reality); stimulation of plantar pressure receptors to reduce adverse adaptations to reduced weight bearing (i.e. prolonged bedrest or microgravity exposure).

1) Feedback Array:
Vibrotactile or electrotactile cutaneous feedback encodes position of foot Center-Of-Pressure and/or weight distribution by modulating one or more of the following: stimulus frequency, stimulus amplitude, location of stimulus or number of active stimulators. This Element(s) is located adjacent to the skin of the leg or thigh. The location of active stimulator(s) on the skin in the transverse plane will directly reflect the location of the foot Center-of-Pressure in the transverse plane.

2) Signal Processor/Controller:
Converts electrical or mechanical signal(s) from Planta Pressure Sensor Array into signal(s) which control the activity of the Feedback Array element(s). May be implemented as a discrete system component or be imbedded within the Plantar Pressure Sensor Array or Feedback Array. Performs an estimation of the position of the Center-of-Pressure under the foot and/or the fraction of body weight supported by the foot. These estimates are then used to produce an appropriate output signal to the Feedback Array. A "dead-zone" may be implemented such that Center-of-Pressure position within a certain range and/or foot load below a certain threshold may produce no output to the feedback elements.

3) Plantar Pressure Sensor Array: Transduces pressure distribution under the foot and transfers that information to the Signal Processor/Controller.

Bipedal Device; only one leg shown. One or more of modules may be held against the skin in a stocking. Sensor array module may be incorporated into a shoe or implemented as a shoe insert. Connection between modules may be wireless. Feedback elements may be incorporated into a a shoe or shoe insert.

We claim:

1. A method for assisting the maintenance of balance during standing or gait, comprising:
   - a sensing means, incorporating sensors placed under each foot, which transduces the magnitude of forces applied to each element of said sensing means and transmits this information to a signal processing means;
   - a signal processing means which immediately converts the signals provided by the sensing means into a signal which controls one or more stimulation means and;
   - a stimulation means which responds to signals transmitted by the signal processing means by stimulating the user in a manner indicative of the forces transduced by the sensing means.
2. The method of claim 1 wherein elements within the sensing means are sensitive to forces oriented perpendicular to the plane of the sensing means.
3. The method of claim 1 wherein elements within the sensing means are sensitive to forces oriented parallel to the plane of the sensing means.
4. The method of claim 1 wherein elements within the sensing means are sensitive to forces oriented parallel to the plane of the sensing means and to forces oriented perpendicular to the plane of the sensing means.
5. The method of claim 1 wherein the sensing means is inserted into a shoe or stocking.
6. The method of claim 1 wherein the sensing means is incorporated within a shoe or stocking.
7. The method of claim 1 wherein the sensing means furthermore consists of one or more sensors implanted into the skin, under the skin, or within the body.
8. The method of claim 1 wherein the signal processing means furthermore incorporates the intermediate steps of:
   - converting the signals transmitted by the sensing means into estimates of the magnitude of the resultant force applied to the sole of each foot and;
   - generating control signals transmitted to the stimulation means that encode the magnitude of the resultant force applied to the sole of each foot.
9. The method of claim 1 wherein the signal processing means furthermore incorporates the intermediate steps of:
   - converting the signals transmitted by the sensing means into estimates of the position of the resultant force applied to the sole of each foot and;
   - generating control signals transmitted to the stimulation means that encode the position of the resultant force applied to the sole of each foot.
10. The method of claim 1 wherein the signal processing means furthermore incorporates the intermediate steps of:
    - converting the signals transmitted by the sensing means into estimates of the orientation of the resultant force applied to the sole of each foot and;
    - generating control signals transmitted to the stimulation means that encode the orientation of the resultant force applied to the sole of each foot.

11. The method of claim 1 wherein the signal processing means furthermore incorporates the intermediate steps of:
    - converting the signals transmitted by the sensing means into estimates of the magnitude and position of the resultant force applied to the sole of each foot and;
    - generating control signals transmitted to the stimulation means that encode the magnitude and position of the resultant force applied to the sole of each foot.
12. The method of claim 1 wherein the signal processing means furthermore incorporates the intermediate steps of:
    - converting the signals transmitted by the sensing means into estimates of the orientation and position of the resultant force applied to the sole of each foot and;
    - generating control signals transmitted to the stimulation means that encode the orientation and position of the resultant force applied to the sole of each foot.
13. The method of claim 1 wherein the signal processing means furthermore incorporates the intermediate steps of:
    - converting the signals transmitted by the sensing means into estimates of the magnitude and orientation of the resultant force applied to the sole of each foot and;
    - generating control signals transmitted to the stimulation means that encode the magnitude and orientation of the resultant force applied to the sole of each foot.
14. The method of claim 1 wherein the signal processing means furthermore incorporates the intermediate steps of:
    - converting the signals transmitted by the sensing means into estimates of the magnitude, position, and orientation of the resultant force applied to the sole of each foot and;
    - generating control signals transmitted to the stimulation means that encode the magnitude, position, and orientation of the resultant force applied to the sole of each foot.
15. The method of claim 1 wherein the signal processing means furthermore incorporates the intermediate steps of:
    - converting the signals transmitted by the sensing means into estimates of the portion of total body weight applied to the sole of each foot and;
    - generating control signals transmitted to the stimulation means that encode portion of body weight applied to the sole of each foot.
16. The method of claim 1 wherein the signal processing means furthermore incorporates the intermediate steps for determining the magnitude of the resultant reaction force applied to each foot sole of:
    - summing the total force applied to each sensor within the sensing means and;
    - dividing this sum by the total body weight of the user.
17. The method of claim 1 wherein the signal processing means furthermore incorporates a means to transmit signals generated by the sensing means to a remote location for further analysis.
18. The method of claim 1 wherein the signal processing means furthermore incorporates a means to record and store signals generated by the sensing means for later analysis.
19. The method of claim 1 wherein the stimulation means furthermore consists of an array of stimulators temporarily affixed to the leg of the user.

20. The method of claim 1 wherein the stimulation means furthermore consists of an array of stimulators incorporated into a stocking.
21. The method of claim 1 wherein the stimulation means furthermore consists of one or more stimulators implanted into the skin, under the skin, or within the body.
22. The method of claim 21 wherein one or more elements of the stimulation means are placed adjacent to or in contact with one or more sensory neurons or sensory nerves.
23. The method of claim 1 wherein the stimulation means produces vibrational stimuli.
24. The method of claim 1 wherein the stimulation means produces electrical or electrocutaneous stimuli.
25. The method of claim 1 wherein the stimulation means produces auditory stimuli.
26. The method of claim 1 wherein the stimulation means produces visual stimuli.
27. The method of claim 1 wherein the stimulation means produces thermal stimuli.
28. The method of claim 1 wherein one or more elements of the stimulation means is located on the legs, trunk, arms, or head of the user.
29. The method of claim 1 wherein the stimulation means consists of an array of stimulators adjacent to or in contact with each leg of the user in a plane approximately parallel to the plane of the ipsilateral foot sole.
30. The method of claim 1 wherein one or more elements of the stimulation means stimulates the soles of the feet.
31. The method of claim 1 wherein the stimulation means responds to the signals transmitted from the signal processing means such that the stimulus amplitudes, frequencies, and locations are indicative of parameters describing the forces applied to the soles of the feet.

32. A method for assisting the maintenance of balance during standing or gait, comprising:
    - a sensing means which transduces the angle between each foot and the ipsilateral lower leg and transmits this information to a signal processing means;
    - a signal processing means which immediately converts the signals provided by the sensing means into a signal which controls one or more stimulation means and;
    - a stimulation means which responds to signals transmitted by the signal processing means by stimulating the user in a manner indicative of the angles transduced by the sensing means.
33. The method of claim 32 wherein elements within the sensing means are sensitive to angles between the foot and the ipsilateral lower leg projected onto a sagital plane.
34. The method of claim 32 wherein elements within the sensing means are sensitive to angles between the foot and the ipsilateral lower leg projected onto a coronal plane.
35. The method of claim 32 wherein the sensing means is inserted into a shoe or stocking.
36. The method of claim 32 wherein the sensing means is incorporated within a shoe or stocking.
37. The method of claim 32 wherein the sensing means furthermore consists of one or more sensors implanted into the skin, under the skin, or within the body.
38. The method of claim 32 wherein the signal processing means furthermore incorporates the intermediate steps of:

- converting the signals transmitted by the sensing means into estimates of the magnitude of the angle between each foot and the ipsilateral lower leg;
- generating control signals transmitted to the stimulation means that encode the magnitude of the angle between each foot and the ipsilateral lower leg.

39. The method of claim 32 wherein the signal processing means furthermore incorporates a means to transmit signals generated by the sensing means to a remote location for further analysis.
40. The method of claim 32 wherein the signal processing means furthermore incorporates a means to record and store signals generated by the sensing means for later analysis.
41. The method of claim 32 wherein the stimulation means furthermore consists of an array of stimulators temporarily affixed to the leg of the user.
42. The method of claim 32 wherein the stimulation means furthermore consists of an array of stimulators incorporated into a stocking.
43. The method of claim 32 wherein the stimulation means furthermore consists of one or more stimulators implanted into the skin, under the skin, or within the body.
44. The method of claim 43 wherein one or more elements of the stimulation means are placed adjacent to or in contact with one or more sensory neurons or sensory nerves.
45. The method of claim 32 wherein the stimulation means produces vibrational stimuli.
46. The method of claim 32 wherein the stimulation means produces electrical or electrocutaneous stimuli.
47. The method of claim 32 wherein the stimulation means produces auditory stimuli.
48. The method of claim 32 wherein the stimulation means produces visual stimuli.
49. The method of claim 32 wherein the stimulation means produces thermal stimuli.
50. The method of claim 32 wherein one or more elements of the stimulation means is located on the legs, trunk, arms, or head of the user.
51. The method of claim 32 wherein the stimulation means consists of an array of stimulators adjacent to or in contact with each leg of the user in a plane approximately parallel to the plane of the ipsilateral foot sole.
52. The method of claim 32 wherein one or more elements of the stimulation means stimulates the soles of the feet.
53. The method of claim 32 wherein the stimulation means responds to the signals transmitted from the signal processing means such that the stimulus amplitudes, frequencies, or locations are indicative of parameters describing the angles between the feet and the ipsilateral legs.

54. A method for assisting the maintenance of balance during standing or gait, comprising:
    - a sensing means incorporating sensors which transduces the magnitude of forces applied to elements of said sensing means located under the feet and transduces the magnitude of the angle existing between each foot and the ipsilateral lower leg and transmits this information to a signal processing means;
    - a signal processing means which immediately converts the signals provided by the sensing means into a signal which controls one or more stimulation means and;

- a stimulation means which responds to signals transmitted by the signal processing means by stimulating the user in a manner indicative of the forces and angles transduced by the sensing means.

55. The method of claim 54 wherein elements within the sensing means are sensitive to angles between the foot and the ipsilateral lower leg projected onto a sagital plane.
56. The method of claim 54 wherein elements within the sensing means are sensitive to angles between the foot and the ipsilateral lower leg projected onto a coronal plane.
57. The method of claim 54 wherein elements within the sensing means are sensitive to forces oriented perpendicular to the plane of the sensing means.
58. The method of claim 54 wherein elements within the sensing means are sensitive to forces oriented parallel to the plane of the sensing means.
59. The method of claim 54 wherein elements within the sensing means are sensitive to forces oriented parallel to the plane of the sensing means and to forces oriented perpendicular to the plane of the sensing means.
60. The method of claim 54 wherein the sensing means is inserted into a shoe or stocking.
61. The method of claim 54 wherein the sensing means is incorporated within a shoe or stocking.
62. The method of claim 54 wherein the sensing means furthermore consists of one or more sensors implanted into the skin, under the skin, or within the body.
63. The method of claim 62 wherein one or more elements of the stimulation means are placed adjacent to or in contact with one or more sensory neurons or sensory nerves.
64. The method of claim 54 wherein the signal processing means furthermore incorporates the intermediate steps of:
    - converting the signals transmitted by the sensing means into estimates of the magnitude of the resultant force applied to the sole of each foot and the magnitude of the angle existing between each foot and the ipsilateral lower leg and;
    - generating control signals transmitted to the stimulation means that encode the magnitude of the resultant force applied to the sole of each foot and the magnitude of the angle existing between each foot and the ipsilateral lower leg.
65. The method of claim 54 wherein the signal processing means furthermore incorporates the intermediate steps of:
    - converting the signals transmitted by the sensing means into estimates of the position of the resultant force applied to the sole of each foot and the magnitude of the angle existing between each foot and the ipsilateral lower leg and;
    - generating control signals transmitted to the stimulation means that encode the position of the resultant force applied to the sole of each foot and the magnitude of the angle existing between each foot and the ipsilateral lower leg.
66. The method of claim 54 wherein the signal processing means furthermore incorporates the intermediate steps of:
    - converting the signals transmitted by the sensing means into estimates of the orientation of the resultant force applied to the sole of each foot and the magnitude of the angle existing between each foot and the ipsilateral lower leg and;
    - generating control signals transmitted to the stimulation means that encode the orientation of the resultant force applied to the sole of each foot and the magnitude of the angle existing between each foot and the ipsilateral lower leg.

67. The method of claim 54 wherein the signal processing means furthermore incorporates the intermediate steps of:
    - converting the signals transmitted by the sensing means into estimates of the magnitude and position of the resultant force applied to the sole of each foot and the magnitude of the angle existing between each foot and the ipsilateral lower leg and;
    - generating control signals transmitted to the stimulation means that encode the magnitude and position of the resultant force applied to the sole of each foot and the magnitude of the angle existing between each foot and the ipsilateral lower leg.
68. The method of claim 54 wherein the signal processing means furthermore incorporates the intermediate steps of:
    - converting the signals transmitted by the sensing means into estimates of the magnitude, position, and orientation of the resultant force applied to the sole of each foot and the magnitude of the angle existing between each foot and the ipsilateral lower leg and;
    - generating control signals transmitted to the stimulation means that encode the magnitude, position, and orientation of the resultant force applied to the sole of each foot and the magnitude of the angle existing between each foot and the ipsilateral lower leg.
69. The method of claim 54 wherein the signal processing means furthermore incorporates the intermediate steps of:
    - converting the signals transmitted by the sensing means into estimates of the portion of total body weight applied to the sole of each foot and;
    - generating control signals transmitted to the stimulation means that encode portion of body weight applied to the sole of each foot.
70. The method of claim 54 wherein the signal processing means furthermore incorporates the intermediate steps for determining the magnitude of the resultant reaction force applied to each foot sole of:
    - summing the total force applied to each sensor within the sensing means and;
    - dividing this sum by the total body weight of the user.
71. The method of claim 54 wherein the signal processing means furthermore incorporates a means to transmit signals generated by the sensing means to a remote location for further analysis.
72. The method of claim 54 wherein the signal processing means furthermore incorporates a means to record and store signals generated by the sensing means for later analysis.
73. The method of claim 54 wherein the stimulation means furthermore consists of an array of stimulators temporarily affixed to the leg of the user.
74. The method of claim 54 wherein the stimulation means furthermore consists of an array of stimulators incorporated into a stocking.
75. The method of claim 54 wherein the stimulation means furthermore consists of one or more stimulators implanted into the skin, under the skin, or within the body.
76. The method of claim 75 wherein one or more elements of the stimulation means are placed adjacent to or in contact with one or more sensory neurons or sensory nerves.
77. The method of claim 54 wherein the stimulation means produces vibrational stimuli.

78. The method of claim 54 wherein the stimulation means produces electrical or electrocutaneous stimuli.
79. The method of claim 54 wherein the stimulation means produces auditory stimuli.
80. The method of claim 54 wherein the stimulation means produces visual stimuli.
81. The method of claim 54 wherein the stimulation means produces thermal stimuli.
82. The method of claim 54 wherein one or more elements of the stimulation means is located on the legs, trunk, arms, or head of the user.
83. The method of claim 54 wherein the stimulation means consists of an array of stimulators adjacent to or in contact with each leg of the user in a plane approximately parallel to the plane of the ipsilateral foot sole.
84. The method of claim 54 wherein one or more elements of the stimulation means stimulates the soles of the feet.
85. The method of claim 54 wherein the stimulation means responds to the signals transmitted from the signal processing means such that the stimulus amplitudes, frequencies, and locations are indicative of parameters describing the forces applied to the soles of the feet.

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FILING RECEIPT

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APR 1 6 2001

Date Mailed: 04/12/2001

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Applicant(s)

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If Required, Foreign Filing License Granted 04/10/2001

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**** SMALL ENTITY ****

Title

Sensory prosthetic for improved balance control

Data entry by : TESHOME, KEFYALEW **Team :** OIPE **Date:** 04/12/2001

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Injury Analysis and Prevention Lab Staff meeting notes March 15 2000

Lars:

- Working on VA grant submission including data from Josef on young and elderly perturbations.
- NJ balance pilot project progressing well. Looked at video from recent classes and implemented some minor modifications that Patrick brought down.
- Site visit by NSBRI Executive Advisory Council. Positive response. Thanks Erik and Pete for help.
- Testing elderly subject today
- Received NIH (old NORA) score. Worse than before, 265, 39.5 %-ile. Will not resubmit this proposal as an R01.

Erik spending most of his time on analyzing data, thesis writing and preparing for final experiments.

Peter setting up for first dissertation committee meeting. He has also developed a neat little state space model for testing of some concepts with respect to diffusion analysis. Will have to provide more info to IRB before approval.

Andreas and Johnny went back to Sweden. Mats here until end of March. He is making some very exciting progress on his foot pressure device project. Ready for presentation in the lab next week.

Alana and Nick back from spring break. Getting ready for more experiments in the lab.

Injury Analysis and Prevention Lab Staff meeting notes April 19, 2000

Lars:

- Last 3 ½ months dominated by work on VA proposal on balance testing and training in the elderly population. Finally submitted last week. This was a terrible time crunch but I think we pulled it off. Thanks to everyone involved include Josef....I have become very unimpressed with some of the literature in the area. Millions of dollars have been wasted on bad studies. In many cases complete unawareness of principles of physical training and exercises. I hope we get a chance to change that.
- NJ balance project is progressing well. The pilot training group graduated yesterday and testing of subjects for the randomized trial is currently going on. Patrick is there testing. We have 10 new fallers for this round. All but one from the pilot group will participate in the TaiChi training. Some new hope for the back pain study. More info from Serge.
- Working on two papers with Josef on lifting data in the young and one review paper with Gerold and a paper with Conrad Wall and Michael McPartland on perturbation data for NSBRI. Interesting results on perturbation recovery of the trunk in vestib patient..

Erik finished his experiments another 10 subjects or so, congratulations. Started analyzing the data and setting up for finalizing his dissertation.

Peter had a meeting with his first meeting with the dissertation committee. Designed a model to help understand stabilogram diffusion parameters.

Mats went back to Sweden. The device he built has been in constant use everyday ever since he left. Some very interesting results coming out already.

Nick is using the pressure device built by Mats to see if normal subjects can improve their balance with increased feedback provided as vibration.

Alana finished testing 21 subjects on subjective scoring by a professional gym judge, stepping threshold, jumping performance and several balance tests on BALDER.

Injury Analysis and Prevention Lab Staff meeting notes May 17, 2000

Lars:

- For the second year in a row I went to the VA research week to represent our ongoing VA related research. It was again located in the entrance of the hospital in Jamaica Plain. I had interesting conversation with 2 patients.
- The randomized balance study in NJ is progressing. Our instructor was injured. New instructor for Tai-Chi and Azar is doing the Swiss Ball training and it appears to be going well. Azar will perform half time testing. Carlo and Serge where there. Patrick back after getting the randomized study up and going. Patrick is writing up the results from the pilot study for a Rehab meeting later this year. More info from Serge and Carlo.
- Struggling to provide a long overdue final report for the VA BAS project. It has been an extraordinary frustrating process with hurdles that would have been unimaginable 3 years ago. Jens has recently provided me with crunched corrected files some of which I was finally able to examine for the first time yesterday. Some of the results are really nice. I am very excited about it. It appears that the imbalance parameter concept
-
- Working on the NSBRI grant renewal with Conrad. Our role will be expanded for next year. Also involved in a new initiative by Chuck Oman and Conrad Wall regarding a vestibular rehab project for NSBRI. It involves a great team of people with expertise in areas from rehab to modeling and exercise science. A perfect mix
- Propose a countermeasure concept and also developa ground based model for space like vestibular insult. We will take a dominating role in this project.
- Continue working on papers with Josef, a review paper with Gerold and a paper with Conrad Wall and Michael McPartland on perturbation data for NSBRI. Also working on a separate paper with Patrick to introduce the Swiss Ball training concept.
- Visit by photographers from National Geographic and NSBRI

Erik furiously analyzing his data and some very interesting findings are coming out. Great progress trying to get a meeting with his committee before the summer
finished his experiments another 10 subjects or so, congratulations. Started analyzing the data and setting up for finalizing his dissertation.

Peter. Designed a model to help understand stabilogram diffusion parameters.

Senior students Nick and Alana finished and did GREAT. Very impressed with their efforts, as well as all the other Center seniors.

$$\frac{X_s}{l_s} = \frac{X_1}{l_1}$$

SCALING OF COP TO REFERENCE SUBJECT (170cm, TALL)

$$X_s = X_1 \frac{l_s}{l_1} = \text{Scaled COP}$$

Now, we have already

$$\langle \Delta X_1^2 \rangle = 2D_1 \Delta t$$

for X_s, this is

$$\langle \Delta X_s^2 \rangle = 2D_s \Delta t$$

$$\frac{l_s^2}{l_1^2}\langle \Delta X_1^2 \rangle = 2D_s \Delta t = \frac{l_s^2}{l_1^2} 2D_1 \Delta t$$

$$\therefore D_s = \frac{l_s^2}{l_1^2} D_1$$

So D gets smaller for taller subjects, D gets larger for smaller subjects

$$\text{or } D_s = \frac{D_1}{\left(\frac{l_1^2}{l_s^2}\right)}$$

$$X_s = \frac{X_1}{\left(\frac{l_1}{l_s}\right)}$$

$$\langle \Delta X_1^2 \rangle = A_1 \Delta t^{2H_1}$$

$$\langle \Delta X_s^2 \rangle = A_s \Delta t^{2H_s}$$

$$\frac{l_s^2}{l_1^2}\langle \Delta X_1^2 \rangle = A_s \Delta t^{2H_s} = \frac{l_s^2}{l_1^2} A_1 \Delta t^{2H_1}$$

$$\log \frac{l_s^2}{l_1^2} + \log \langle \Delta x_1^2 \rangle = \log A_s + 2H_s \log \Delta t$$
$$= \log\left(\frac{l_s^2}{l_1^2}\right) + \log A_1 + 2H_1 \log \Delta t$$

$$\log A_s + 2H_s \log \Delta t = \log \frac{l_s^2}{l_1} + \log A_1 + 2H_1 \log \Delta t$$

$$\therefore \log A_s = \log \frac{l_s^2}{l_1} + \log A_1 \quad \text{and} \quad 2H_s \log \Delta t = 2H_1 \log \Delta t$$

$$H_s = H_1$$

7/2/00 Met with Aristides Veves from BIDMC-Joslin Foot Clinic. Very interested in collaboration. Sees 15000 patients a year. Doesn't think that falls are a major problem in diabetic neuropathy- foot ulcers are his main concern. Very interested in trying to feedback lost pain information to eliminate the production of foot ulcers. Referenced "Anderson" regarding small muscle neuropathy and its effects on ulcer production. Will visit here on the week of the 17th of July.

I need to send him my info on balance losses in neuropathy patients. I also need to find more info about other patient populations. Look into foot ulcer prevention possibilities for our device.

Mary ...

VESTIBULAR PROSTHESIS (CONRAD WALL)

Hi Pete,
Conrad ran a prelim analysis on RMS sway from the vest experiment and it was clear that the vibration ques helped a lot. The patient, who actually is a pilot.... said that he only focused on the vibration ques and he did not feel any other sway ques. Very interesting. Sway during playback with vibration feedback was lower than standing stationary without vibration, probably not significant with 10 trials but still.... Here are the results.

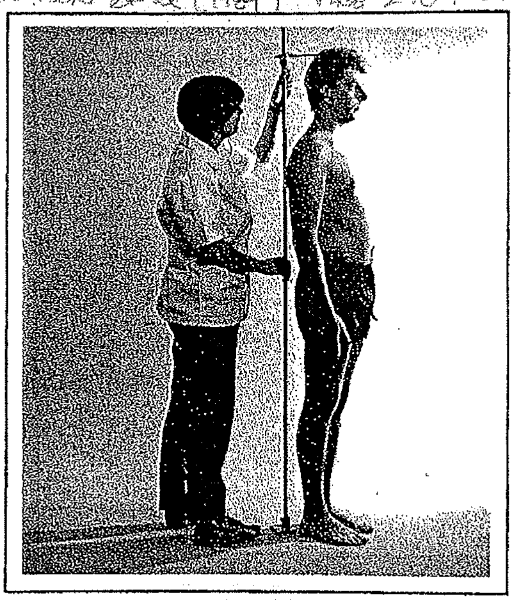
novest, stationary 0.36Y0.08 (+/-)
vest on, stationary 0.24Y0.05
this difference is sig at p = 9.2817e-04 [2-tailed t test]

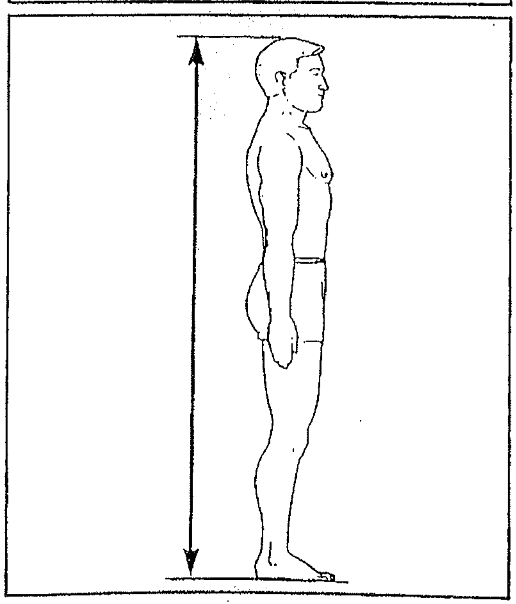
novest, playback 0.55Y0.14
vest on, playback 0.31Y0.05
this difference is sig at p =6.0326e-05

Maybe you can show me your Matlab routine for the SD parameters on Monday. It will be very interesting to see how they will come out. I think we should do the same experiment with the foot device. After hearing the comments from this subject I am less concerned about the alarm exeriment although we should do that as well. However, the fact that he could ony feel sway from the vibration cues and he was able to decrease sway shows that it must be directional specific. We should also meet and discuss with Conrad how/if we should combine any efforts between these two devices.

Subjective opinion, but lends credence to the suggestion that direction info is used.

GORDON et al (1989) PAGE 210 : STATURE





CdM

THE PERCENTILES

FEMALES CM	FEMALES INCHES		MALES CM	MALES INCHES
148.32	58.39	1ST	160.27	63.10
150.18	59.13	2ND	162.05	63.80
151.31	59.57	3RD	163.17	64.24
152.78	60.15	5TH	164.69	64.84
154.97	61.01	10TH	167.03	65.76
156.43	61.59	15TH	168.62	66.39
157.58	62.04	20TH	169.89	66.88
158.58	62.43	25TH	170.99	67.32
159.48	62.79	30TH	171.98	67.71
160.32	63.12	35TH	172.90	68.07
161.14	63.44	40TH	173.78	68.42
161.93	63.75	45TH	174.64	68.76
162.72	64.06	50TH	175.49	69.09
163.53	64.38	55TH	176.34	69.43
164.35	64.70	60TH	177.21	69.77
165.21	65.04	65TH	178.11	70.12
166.13	65.40	70TH	179.06	70.50
167.13	65.80	75TH	180.09	70.90
168.27	66.25	80TH	181.24	71.35
169.59	66.77	85TH	182.57	71.88
171.27	67.43	90TH	184.23	72.53
173.73	68.40	95TH	186.65	73.48
175.28	69.01	97TH	188.16	74.08
176.39	69.44	98TH	189.24	74.50
178.04	70.09	99TH	190.87	75.14

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UMDNJ Cross Sectional data EO

	Dxs	Dys	Dxl	Dyl	Hxs	Hys	Hxl	Hyl
Fallers	14.71	22.02	1.31	2.86	0.61	0.54	0.17	0.21
SD	19.13	17.36	1.61	2.59	0.07	0.09	0.10	0.12
Non-fallers	4.20	8.99	0.52	1.26	0.61	0.56	0.22	0.25
SD	4.49	6.40	0.87	0.90	0.06	0.06	0.10	0.11
p<	0.0067	0.0006	0.0306	0.0037	0.9096	0.5198	0.0982	0.2703

	Ctx	Cty	Cdx	Cdy
FALLERS	1.19	0.85	29.93	35.52
SD	0.40	0.18	30.47	30.27
Non-FALLERS	1.04	0.89	9.13	14.89
SD	0.25	0.13	11.57	10.38
p <	0.1153	0.4180	0.0017	0.0014

1% lidocaine, 1:10 8.4% Na. bicarb, 1:200,000 epi, 12 U/mL hyaluronidase

Foot Size, Area (US, cm2)			**9**	191	**13**	248.4
Penetration (cm2/mL)			10	7	10	7
# Injections			19.100	27.286	24.840	35.486
Lidocaine	(mg/mL)	18.000	343.800	491.143	447.120	638.743
Bicarbonate	(mg/mL)	8.400	160.440	229.200	208.656	298.080
Epinephrine	(mg/mL)	5.00E-06	9.55E-05	1.36E-04	1.24E-04	1.77E-04
Hyaluronidase	(IU/mL)	12.000	229.200	327.429	298.080	425.829

Lidocaine. Not to exceed 7mg/kg 500mg Leitkin
Epinephrine. Not to exceed 500μg Dieckbach (neuro-...)
Valley

1. Introduction

It has been estimated that 4.5 million Americans, including 20% of the elderly population, may be suffering from peripheral neuropathies, largely as a consequence of diabetes [1, 2]. Epidemiological evidence has linked peripheral neuropathies (PN) to an increased risk of falling [3, 4]. Peripheral neuropathic patients exhibit decreased stability while standing [5] as well as when subject to simulated slipping conditions [6]. Since the patients in these studies were restricted to those without measurable motor deficits, it is apparent that sensory information from the periphery (i.e. ankles & feet) is important for the maintenance of standing balance. It remains unclear, however, to what extent specific foot and ankle sensory system(s) are involved in balance control.

To elucidate the role of foot afferents in balance control, postural studies have employed the temporary removal of afferent sensation. Common methods for reversible deafferentation included ischemic [7, 8] or hypothermic anesthesia of the foot [9, 10]. While these studies attempted to focus specifically on the role of cutaneous mechanoreceptors in balance control, the conclusions reached may be questioned based upon the authors' inability to specifically target the foot sole cutaneous afferents for anesthesia. The anesthetic techniques used can be assumed to have affected muscle spindle, Golgi tendon organ, and joint mechanoreceptor afferents (and, to a lesser degree, muscle efferents within the foot), leaving the specific role of plantar cutaneous mechanoreceptors unclear. Other researchers have relied on the direct stimulation of foot sole afferents by vibration [11, 12]. This method, however, involves a non-physiological stimulus and leaves open the possibility of stimulating other sensory afferents within the foot.

The current project is an attempt to isolate the role played by plantar cutaneous mechanoreceptors in the maintenance of balance under static and dynamic conditions. All subjects will undergo anesthesia which specifically targets the cutaneous mechanoreceptors of the foot sole, eliminating confounding effects on other afferent and efferent systems of the foot. In the first experiment, subjects will perform series of static balance tests on a stationary force platform before and after anesthesia. In a second experiment, subjects will perform balance tests before and after anesthesia on a specially instrumented moving force platform designed to simulate slipping conditions. Kinematic and kinetic measurements under both normal and anesthetized conditions will be used to determine the effect of the elimination of plantar cutaneous mechanoreceptor information on balance control.

2. Hypotheses and Specific Aims

Specific Aim 1: Characterize the role of plantar cutaneous afferents in the maintenance of upright balance during quiet standing.

Hypothesis 1: Feedback control of posture includes a non-linear "deadzone" in which small deviations from a sensory set position produce no reactive motor response. A reduction in cutaneous sensation from the foot sole will increase the range of this deadzone, resulting in increased center-of-pressure deviations before reactive postural corrections occur. These changes will be manifest in an increase in short-term diffusion coefficients, critical times, and critical displacements during still stance. Enhanced cutaneous foot sole sensation will produce opposite effects.

Experiment 1: Ten healthy subjects will perform ten 30 second trials of still stance with three different tasks: standing bipedal with and without vision, and in a unipedal stance with vision. These tasks will be repeated under three conditions: normal sensation, enhanced plantar pressure, and reduced plantar pressure sensation. Net ground reaction forces will be measured and center-of-pressure (COP)

trajectories calculated. Results will be characterized in terms of stabilogram-diffusion parameters as well as traditional COP statistics.

Specific Aim 2: Characterize the role of plantar cutaneous afferents in the maintenance of upright balance during simulated slips.

Hypothesis 2: Cutaneous foot-sole afferent information modulates postural responses to perturbations. The reduction of foot-sole sensory information will result in reduced amplitude and/or increased latency of postural responses to simulated slips. Likewise, enhanced plantar pressure sensation will result in increased amplitude and/or reduced latency of postural responses to simulated slips.

Hypothesis 3: Cutaneous foot-sole afferent information is used in the selection of appropriate postural control strategies. The reduction of foot-sole sensory information will result in decreased reliance on a hip strategy, manifest as a reduction in net hip torque in response to a given support surface perturbation.

Experiment 2: Ten healthy subjects will undergo repeated support surface translations under three conditions: normal sensation, enhanced plantar pressure sensation, and reduced plantar pressure sensation. Center of pressure trajectories, body segment kinematics, and postural muscle activity will be measured. Reactions will be characterized in terms of response latencies and order of muscle activation.

3. Background and Significance

3.1 Feedback Control of Posture

The human balance control system incorporates a large number of postural muscles and joints, creating a statically indeterminate system with many degrees of freedom. Also included in this system are sensory afferents which provide feedback regarding body position and orientation. The basic task of these feedback systems is to estimate the location and trajectory of the body center-of-mass (COM). Feedback-induced movements may be classified as reflexive, automatic, or volitional (see Table 1).

Table 1
Properties of the Three Movement Systems (from Nashner 1993)

	Movement Systems		
Property	Reflex	Automatic	Volitional
Mediating pathway	Spinal Cord	Brain stem & subcortical	Brain stem & cortical
Mode of activation	External stimulus	External stimulus	Self-generated or external stimulus
Response properties	Localized to point of stimulus, highly stereotyped	Coordinated among leg & trunk muscles, stereotyped but adaptable	Limitless variety
Role in posture	Regulate muscle forces	Coordinate movements across joints	Generate purposeful behaviors
Response time	Fixed at ~40ms	Fixed at ~100ms	Varies with difficulty, >150ms

Impaired standing balance occurs when either a) the position of the COM with respect to the base of support is inaccurately sensed; or b) the automatic movements required to bring the COM into a balanced position are

untimely or poorly coordinated [13]. Three basic sensory systems are employed in balance control. The vestibular system encodes linear (including gravitational) and angular accelerations of the head with respect to inertial space. Vision measures the orientation of the eyes with respect to the surround. The somatosensory system includes a number of sensory sub-systems that provide information regarding the orientation of body segments with respect to each other and the external environment. The somatosensory system has at least four sub-systems involved in the control of standing balance. Golgi tendon organs encode muscle loads, while muscle spindles are sensitive to both muscle length and velocity of stretch. Joint mechanoreceptors provide information regarding contact forces occurring within joints. Cutaneous mechanoreceptors encode pressure and skin stretch under the soles of the feet, providing feedback regarding the distribution of body load onto the support surface.

Sensory systems involved in postural control are not truly redundant, as none of them directly sense the location of the body COM. The existence of highly functional patients with vestibular deficits, blindness, or peripheral neuropathies does indicate that some degree of balance control may be retained despite significant sensory losses. Table 2 summarizes the importance of these sensory systems under different conditions.

Table 2
Utilization of the Senses for Balance (adapted from Nashner 1993)

Sense	Reference	Conditions Favoring Use	Conditions Disrupting Use
Vestibular	Gravity and inertial space	Irregular or moving support and moving surrounds or darkness	Unusual motion environments
Visual	Surrounding objects	Fixed visible surrounds and irregular or moving support	Moving surrounds or darkness
Somatosensory	Support surface and limb orientations	Fixed Support Surface	Irregular or moving support surface

The task of the postural control system is to maintain the COM over the base of support, which is formed by the feet in the standing position. Maintenance of COM position during unperturbed stance is generally accomplished through activation of the ankle musculature. This suggests a simple inverted pendulum as a mechanical model for quiet stance (see Figure 1). In this model, torque produced across the ankle joint causes an acceleration of the COM. Passive stiffness of the ankle joint is insufficient to maintain upright balance [14, 15]; active muscle contractions are required. Amplitude and timing of the required active postural corrections are modulated by feedback from the vestibular, visual, and somatosensory systems. Despite the afferent information available regarding body position, however, it is impossible for a person to stand perfectly motionless. Volitional movements, reflex responses, and involuntary muscle force variations [16] prevent the maintenance of true equilibrium. Assuming the feet do not move with respect to the ground, torque production at the ankle also results in a corresponding change in the location of the resultant ground reaction force, or center-of-pressure (COP). Relatively simple to acquire, the COP is commonly used in balance control studies to characterize body sway. Displacements of the COP during quiet stance may provide information regarding passive and active control mechanisms [17-20].

Slips, or translations of the base of support with respect to the inertial reference, are a common form of balance perturbation encountered in everyday life. Slipping conditions are simulated in the laboratory by horizontal translation of the support surface. Automatic postural responses to support surface translations in the sagittal plane are roughly classified as implementations of ankle, hip, or step "strategies". The ankle strategy, normally seen in response to slow support surface translations, is characterized by a proximal to distal pattern of muscle activation. Corrective torque is initiated across the ankle joint, with stabilizing torques at the knee and hip following in succession. Translations that might otherwise require compensatory ankle torques that would lift the feet off the ground typically trigger abrupt flexion or extension of the hip joint. This hip strategy is characterized by a proximal to distal pattern of muscle activation. The hip strategy is seen in response to slow translations when the support surface is smaller than the feet [21] or in response to fast support surface translations [22, 23]. Intermediate support surface lengths or perturbation velocities elicit more complicated responses that combine elements of the pure ankle and hip strategies [21-23]. Stepping responses may be seen in large magnitude and/or high velocity support surface translations. Early automatic responses (ankle and/or hip strategy) occur before a step is executed despite the fact that step responses are initiated before the limits of stability have been reached [24].

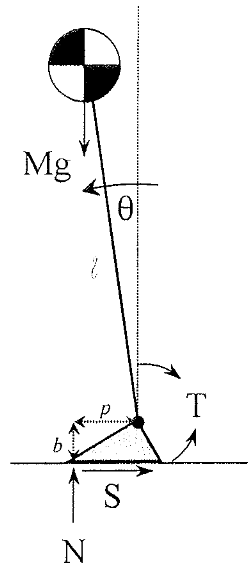

Figure 1: **Inverted Pendulum Model of Quiet Stance.** The model is defined by the equations:

$$Ma_{vert} = N - Mg$$
$$Ma_{hor} = S$$
$$I\ddot{\theta} = Mgl\sin\theta - T$$
$$T = Np - Sb$$

where it is assumed that the foot does not move with respect to the support surface.

3.2 Peripheral Neuropathy and Balance Control

An estimated 4.8 to 6.4 million Americans exhibit symptomatic diabetic peripheral neuropathy (DPN), comprising 30-40% of the U.S. diabetic population [2, 25, 26]. The prevalence of DPN may be as high as 50% in diabetics over 60 years of age. When added to an estimated 10% of the non-diabetic elderly population suffering from peripheral neuropathies (PN) [25], up to 20% of the elderly population may be affected by peripheral neuropathies [1]. The most common form of DPN is a distal symmetric sensory neuropathy [26], which begins with a loss of sensation in the fingers and toes and spreads proximally as the condition progresses [27]. In addition to the large percentage of diabetics, peripheral neuropathies affect approximately one third of AIDS patients [28, 29]. Other conditions that may result in peripheral neuropathies include Gullian-Barre syndrome, Charcot-Marie-Tooth disease, and lead poisoning.

Two basic hypotheses have been proposed to explain the cause of diabetic distal symmetric polyneuropathy. The first is based upon the concept that basic metabolic changes in the axon, neural cell body, or Schwann cells leads to irreversible axonal damage. Peripheral nerves are longer and therefore more susceptible to this type of damage; sensory axons may be at greater risk because they are smaller in diameter and less heavily myelinated. Another hypothesis is that the nerve injury is ischemic in origin, with greater damage in the periphery due to poor circulation [27]. In either case, sensory nerves carrying balance-related feedback from muscle spindles, tendon organs, joint mechanoreceptor, and cutaneous mechanoreceptors are likely to be affected. By exciting muscle spindles through tendon vibration, van Deursen *et al.* (1998) confirmed that DPN patients had deficits somewhere in the muscle spindle systems surrounding the ankle [37]. Likewise, studies have documented increased thresholds for the perception of cutaneous pressure stimuli in DPN patients [25, 32, 38, 39]. Microneurographic recordings from individual cutaneous mechanoreceptors in DPN patients show a decreased ability to transmit sustained action potential trains in response to sustained pressure [40].

Several studies have attempted to explain neuropathy-based balance deficits in terms of reduced somatosensory feedback from the foot and ankle. When standing on a slowly tilting support surface that induced a passive

plantar/dorsiflexion of one ankle, DPN patients showed significantly increased thresholds for the conscious perception of the applied ankle rotation when compared to diabetic and non-diabetic controls [35]. Likewise, peripheral neuropathy patients exhibited increased thresholds for the perception for ankle inversion/eversion [36]. While these results suggest degradation of ankle muscle proprioception and/or ankle joint mechanoreception, there is some evidence that plantar cutaneous sensory deficits may also be involved. Patients in the aforementioned inversion/eversion study showed an improvement in their perception threshold when they increased the load on one foot by adopting a unipedal stance. There was no difference between the thresholds of patients and controls when the foot was unweighted. These results suggest that cutaneous sensation from the foot sole may play an important role in the perception of ankle inversion/ eversion. Using a specially designed apparatus which passively plantar/dorsiflexed the ankle with minimal foot sole contact, however, DPN patients still demonstrated an increased perception threshold for ankle rotation [37]. Both plantar pressure sensors and ankle propriceptors have therefore been implicated in the perception of ankle position during weightbearing. It is clear that deficits in this sensation could pose a serious risk of fall-related injuries during stance and ambulation.

Neuropathic patients also demonstrate abnormalities in their response to sudden balance perturbations. Inglis *et al.* (1994) studied the onset of muscle responses to backward translations of the support surface in DPN patients and controls. They found that while DPN patients used an appropriate muscle synergy (ankle strategy) to regain balance, the onset of muscle activation was delayed by 20 to 30ms. They also found that DPN patients showed a reduced ability to scale the magnitude of their responses to the velocity of the perturbation [6]. In contrast, however, Simmons *et al.* (1997) found that DPN patients were more likely to revert to a hip strategy in response to anteroposterior perturbations rather than the ankle strategy seen in normal subjects [33].

Given the importance of somatosensory feedback in posture control, it is not surprising that patients suffering from sensory neuropathies demonstrate balance deficits. Peripheral neuropathies have been strongly linked to the risk of fall-related injuries [1, 4, 30] as well as a reduced perception of safety in unfamiliar physical surroundings [30]. DPN patients exhibit greater sway during quiet stance than matched control subjects, suggesting a greater degree of postural instability [27, 31-33]. Richardson and colleagues found that moderate peripheral neuropathy in elderly subjects was associated with a dramatic reduction in their ability to maintain a unipedal stance [34], indicating a potential gait instability.

3.3 Microgravity Adaptation and Balance Control

Upon return to terrestrial gravity, astronauts exhibit noticeable changes in their ability to maintain balance. During quiet stance, they demonstrate increased body sway amplitude [41, 42] and increased tremor [43, 44]. Astronauts' ability to compensate for external postural perturbations is also degraded [42, 44]. While the source of these postural deficits remains unclear, one of the afferent feedback systems which has been implicated is that of the plantar cutaneous mechanoreceptors. Under microgravity conditions, foot sole pressure receptors remain largely unloaded. The loss of foot pressure sensation in microgravity appears to be directly related to a suppression of anticipatory postural adjustments associated with rapid arm movements [45]. After long-term microgravity exposure, plantar afferents may exhibit increased vibration sensitivity for 36 or more days post-flight [44]. Unfortunately, further elucidation of the role played by plantar sensitivity on post-flight balance control is confounded by concurrent changes in vestibular function [42], joint proprioception [43, 44], and motor function [44, 46]. Understanding of the contribution of plantar afferents to post-flight postural instabilities therefore requires a ground-based model that can specifically target these receptors.

3.4 The Role of Plantar Cutaneous Afferents in Balance Control

The role of the foot sole cutaneous afferents in normal balance control is the target of the proposed doctoral dissertation project. Among the various somatosensory systems involved in balance control, cutaneous sensation is of particular interest for a number of reasons. Plantar cutaneous sensation is the most obvious and earliest sensation lost as a result of diabetic distal symmetric polyneuropathy. Plantar pressure sensation is well correlated with balance deficits associated with DPN and may be important for the perception of ankle position. Increased sensitivity of foot sole afferents may contribute to postural instabilities associated with microgravity adaptation. A simple inverted pendulum model for quiet stance predicts that the position of body COM can be internally computed by the CNS as a simple function of normal force gradient and shear force under the foot soles [47]. There are practical reasons for choosing to study plantar cutaneous afferents as well. Other somatosensory organs, such as muscle spindles or joint mechanoreceptors, are sensitive to stimuli that are not easily measured externally. In contrast, ground reaction forces under the foot soles are easily recorded, making a study of the role of plantar cutaneous sensation in balance more likely to be fruitful. Finally, because plantar pressures can be recorded, the information gained from this study could be used to implement a sensory substitution prosthetic designed to replace lost information from the foot soles and improve postural stability.

3.4.1 Overview of the Tactile Sensory System

Mechanoreceptors in human glabrous (non-hairy) skin are typically categorized by their response properties and the size of their receptive fields. Fast-adapting, also called rapidly-adapting (RA) mechanoreceptors respond preferentially to abrupt changes in pressure applied to the overlying skin layers. In contrast, slowly-adapting (SA) mechanoreceptors produce repeated discharges to sustained pressure stimuli. The most superficial mechanoreceptors (Type I) have relatively small receptive fields, while the deeper receptors (Type II) are excited by larger receptive fields. Table 3 outlines the response characteristics of the four types of cutaneous, non-nociceptive mechanoreceptors found in glabrous skin. These mechanoreceptors are located at the termination of small myelinated (Type II , or Aβ) sensory nerve fibers.

Table 3
Properties of (non-nociceptive) cutaneous mechanoreceptors in glabrous skin

			Sensitivity[51]			
Type	Common Name	Receptive field size	Sustained pressure	Transient pressure	Skin stretch	Conscious sensation in isolation [52]
SAI	Merkel disk	small	irregular	< 1kHz	no	local pressure
SAII	Ruffini corpuscle	large	regular	high firing rate on pressure increase	yes	none[53]
RAI	Meisner corpuscle	small	no	10-100Hz on increased pressure	no	local flutter
RAII	Pacini corpuscle	large	no	30-1000Hz rectified	no	diffuse vibration

Mechanical stimuli are transduced in the skin and conducted through the dorsal column-medial lemniscal spinal pathway to the thalmus and on to the somatosensory cortex. Some tactile sensation may be carried by the anterolateral pathway as well. The perceived intensity of a mechanical stimulus is thought to follow a power law: $I = K (S - S_0)^n$, where S_0 is the stimulation threshold, S is the suprathreshold stimulus, K is constant, and I is the perceived intensity [48, 49]. Perceptual thresholds for sustained pressure are typically measured using a series of monofilaments of varying stiffness. Subjects are asked if they can feel a sensation when the filament tip is pressed against the skin until the filament buckles. Typical perceptual thresholds of the healthy foot sole are ~4.40 Units (300 kPa) for the metatarsal heads and ~5.12 Units (790 kPa) for the heel [38]. Two-point

discrimination thresholds at the metatarsal heads and heel average 21mm and 35mm respectively using pairs of vibrating indenters operating at 200Hz with amplitudes of 0.1mm [50].

Nociceptive receptors in the plantar skin are responsible for initiation of the classic withdrawal reflex produced by a painful stimulation such as contact with a sharp object. Non-nociceptive mechanoreceptors have been implicated in spinal reflexes as well as automatic postural responses. Electrical stimulation of the posterior tibial and sural nerves at the ankle or the medial plantar nerve at the metatarso-phalangeal joint produce a radiating paresthesia (tingling) sensation in portions of the foot sole (see Figure 2). Rossi *et al.* (1996) studied automatic responses of the tibialis anterior (TA) muscle to stimulation of the medial plantar nerve while subjects were seated. They reported a positive TA response which decreased in threshold and latency with increasing background muscle activation. Estimates of conduction velocity were consistent with Aβ nerve fibers rather than nociceptive afferents. [54]. While these results from seated tests might suggest a functional cutaneous automatic response during standing, it has been demonstrated that cutaneous "reflexes" are dependent on the task performed [55].

While standing, electrical stimulation of the sural nerve produced automatic responses in active muscles only. In bipedal stance, the predominant responses in the first 100ms after sural stimulation were inhibition of TA [55,56] and soleus as well as facilitation of lateral gastrocnemius and peroneus longus (PL) [56]. The direction of response (facilitation or inhibition), however, may be somewhat variable [55]. The strong facilitory response in PL to sural stimulation, mimicking stimulation of the lateral edge of the sole, suggests an active role of this area in the control of ankle inversion/ eversion. It must be noted, however, that electrical stimulation of "cutaneous" nerves via surface or large intraneural electrodes excites muscle and joint proprioceptors as well as purely cutaneous fibers. Conclusions regarding activation of reflex and automatic postural responses by cutaneous mechanoreceptors must be made with caution until detailed microneurographic studies during upright stance have been performed.

3.4.2 Balance Control Studies Targeting Plantar Afferents

The literature regarding the role of plantar afferents in normal balance control can be separated into studies that focus on quiet stance and those that focus on postural reactions to dynamic support conditions. Both of these categories can be further divided into those involving modifications to the support surface and those that directly affect the sensory capability of the foot sole.

3.4.2.1 Support Surface Modifications During Quiet Stance

Watanabe and colleagues (1980, 1981) reported increased high frequency (3-5Hz) sway when subjects stood on a uniformly spaced matrix of 2mm-diameter shotgun balls intended to increase plantar pressure sensation [57]. Their results were more pronounced in the mediolateral direction. Since H-reflexes were not affected, the authors concluded that the increase in sway was not spinal in origin but must be attributed to more central neural mechanisms [58]. In contrast to these results, Kavounoudias *et al.* (1999) observed that vibration of the plantar forefoot and heel at the same frequency did not increase sway. Since the response of vibration-sensitive cutaneous mechanoreceptors is linear with vibration frequency [59], their paradigm was believed to simulate a uniform increase in pressure to the foot soles. A frequency difference between the forefoot and heel, simulating at plantar pressure gradient, did provoke a correlated antero-posterior (AP) movement of the COP. The large latencies found in these experiments (0.9 +/- 0.4s) [12] make this response of questionable utility as a correction for postural perturbations.

3.4.2.2 Plantar Sensory Modifications During Quiet Stance

Studies involving a reduction of plantar sensation during quiet stance have relied on hypothermic or hypoxic anesthesia of the foot. Magnusson *et al.* performed two studies of COP deviations after their subjects' feet were immersed in icewater for approximately 20 minutes. In the first study, the authors noted that AP body sway velocity increased with cooling of the feet. This effect of cooling persisted even when the Achilles tendon was vibrated to excite the spindles of the triceps surae muscles. They concluded that the influence of plantar pressure sensors on reducing postural sway velocity was not suppressed by excitation of the ankle muscle stretch receptors. This effect was more prominent when the subjects eyes were closed, demonstrating a dominant influence of vision on balance control during quiet stance [10]. In the second study, subjects were perturbed with transcutaneous electrical stimulation of the vestibular nerves. The authors noted greater sway amplitude and variance in the mediolateral direction when the feet were cooled. They concluded that the plantar pressure receptors were especially important for the adaptation to erroneous vestibular information [9]. This notion is supported by Enbom *et al.* (1991) who reported an increased reliance on foot sole pressure information in children suffering from congenital bilateral vestibular loss [60]. It must be noted, however, that immersion of the feet in icewater up to the level of the ankle may reduce foot muscle proprioception and force production capabilities as well as cutaneous sensation. It is therefore difficult from these studies to draw conclusions specific to foot sole cutaneous function.

Hypoxic anesthesia of the foot occurs as a result of ischemia, typically induced by the application of a blood-pressure cuff to the ankle or leg. Mauritz *et al.* (1980) found increased AP sway at all frequencies, with a large peak at 1Hz, when afferent sensation was blocked by pneumatic cuffs on the thighs of three healthy subjects. The authors noted that the 1Hz peak was lost when the cuffs were moved to the ankles of one subject, suggesting that this sway was associated with ankle muscle proprioceptors rather than foot afferents [61]. Horak *et al.* (1990) studied quiet stance under a number of sensory conditions including altered vision and/or ankle proprioception. They noted no detectable change in sway magnitude when ischemia was induced below the ankles [8]. In contrast, Hayashi *et al.* (1988) described an increase in 3Hz sway induced by vibration of the Achilles tendon when ischemia was induced below the ankle. As a possible explanation, they suggested that increased ankle muscle proprioception with decreased plantar sensation might induce oscillations in the posture control system. This explanation is bolstered by the fact that 3Hz oscillations are also seen in patients with atrophy of the cerebellar anterior lobe, which receives cutaneous and proprioceptive input from the limbs [62].

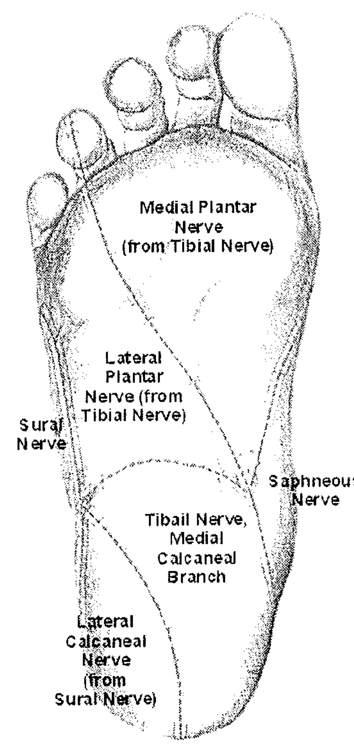

Figure 2
Cutaneous Innervation of the Plantar Sole

It appears from the aforementioned studies that stimulation of the soles can produce postural effects in the absence of corresponding proprioceptive input from the ankle muscles [12, 57, 58]. A decrease in afferent sensation from the foot may increase the velocity of sway but not necessarily the net amplitude [8, 10, 62]. The sensorimotor test battery used by Horak and colleagues is purported to selectively disrupt visual and somatosensory feedback by sway-referencing the support surface and visual surround. It is apparent, however, that while tilts of the support surface with body sway eliminate rotation of the ankle joint as a source of useful feedback, this motion does not eliminate useful somatosensory information from the foot. Normal subjects show little increase in sway in response to misleading vision and ankle muscle proprioception because they are able to compensate using available vestibular and foot sensation. Results are little changed after hypoxic anesthesia of the feet [8], suggesting that vestibular inputs may be sufficient to control balance during quiet stance. Simmons *et al.* (1997), however, found that DPN patients (foot and possibly ankle sensory

deficits) had increased sway when subjected to the same test battery [33]. These conflicting results are especially surprising since the DPN patients had years to adapt to their sensory loss whereas the ischemic subjects were naive. The apparent conflict could be due to flawed foot sensation or undiagnosed vestibular deficits in the DPN group. Patients with known vestibular deficits, however, were unable to maintain balance in the face of misleading vision and ankle muscle proprioception [8]. These results suggest that feedback from foot afferents is not sufficient by itself to control balance.

3.4.2.3 Support Surface Modifications During Dynamic Balance Conditions

Chiang and Wu (1997) studied the effect of a compliant surface on the dynamic response to 60°/s toes-up tilts of the support surface. They monitored both ankle angle and the fore-aft plantar pressure difference as a function of time. Ankle angles were the same on rigid and compliant surfaces for the first 30ms, producing no changes in the short latency stretch reflex response of gastrocnemius. They demonstrated ~5ms delays in the medium-latency (gastrocnemius) and long-latency (tibialis anterior) automatic muscle responses. Since the compliant surface caused a decrease in the slope of the plantar pressure differential curve, these delays could be evidence that fore-aft pressure differences triggered the automatic postural responses. It is impossible, however, to rule out later changes in ankle angle as the cause of the response delays [63, 64].

Do and Roby-Brami (1991) examined automatic responses initiated to prevent falling after being released from a forward lean. They found that when plantar stimulation was increased by supporting the feet only at the heel and toes, subjects initiated and completed the initial step earlier [65]. Horak & Nashner (1986) showed that standing on a shortened support surface resulted in a switch from an ankle strategy to a hip strategy in response to backward surface perturbations [21]. Under the same conditions, patients with vestibular deficits appeared incapable of switching to the hip strategy. These results were taken as evidence that the hip strategy was dependent on vestibular inputs [8]. Runge *et al.* (1998), however, demonstrated that with normal support surface widths (and, hence, normal somatosensation from the leg and foot), vestibular patients did respond to fast backward surface translations with a hip strategy. Their results suggest that the hip strategy is actually dependent on somatosensory input from the foot and ankle rather than the vestibular system [22].

Maki *et al.* (1999) studied postural responses after sensation from the foot sole was enhanced by attaching polyethylene tubing to perimeter of the soles. They reported that elderly subjects were less likely to take more than one forward step in response to backward surface translations. This result suggested that increase heel pressure feedback aided accurate shifting of weight during stepping reactions. Young subjects were less likely to take a backward step in response to forward perturbations, when heel pressure is maximized. Both young and elderly showed smaller posterior COP excursions in response to small, continuous AP surface movements. The authors concluded that sensation from the rearfoot may be more heavily reliant on cutaneous mechanoreceptors due to the lack of joint and muscle proprioceptors in that region [66, 67].

3.4.2.4 Plantar Sensory Modifications During Dynamic Balance Conditions

Several dynamic balance studies have attempted to target foot afferents by inducing hypoxic anesthesia of the foot with a pressure cuff around the ankle. Diener *et al.* (1984) noted no change in muscle responses to rapid (>60°/s) toes-up tilts of the support surface after ischemia of the feet. Loss of foot sensation did induce increased postural sway in response to low frequency (0.3Hz) oscillating tilts of the support surface [7]. These results conflict with the conclusions reached by Chiang and Wu [63, 64] regarding the importance of plantar pressures in mediating the medium and long latency muscle responses to sudden surface tilts. The source of this apparent conflict may lie in the plasticity of the postural control system. It is possible that normal automatic postural responses to sudden surface tilts are normal when foot sensation input is totally absent, but delayed in the presence of conflicting somatosensory information.

Horak *et al.* (1990) found that ischemia of the feet did not result in delayed or disorganized responses to AP surface translations but did affect the choice of postural strategy to counter the perturbation. After ischemia, subjects tended to adopt a hip strategy, rather than the ankle strategy employed under normal conditions. These results are an interesting contrast to those presented by Inglis *et al.* (1994), who used the same perturbations but demonstrated delayed and disorganized responses by subjects suffering from DPN. Results from experiments using ischemia are difficult to interpret, however, since the technique can be assumed to reduce intrinsic foot proprioception and possibly of foot muscle function as well. They are also difficult to repeat, as the technique can be quite painful for the subjects.

Thoumie and Do (1996) examined the effects of deafferentation on postural responses to sudden falls from a forward lean. Their subjects included normals before and after ischemia or tibial nerve anesthesia of one foot as well as patients suffering from unilateral loss of the Achilles tendon reflex. They reported that loss of foot afferents did not affect muscle latencies but did reduce the magnitude of ipsilateral soleus activity. This effect was attributed to decreased facilitation of soleus motor neurons by interneurons normally excited by plantar cutaneous afferents. The effects noted in this study are particularly difficult to interpret due to the experimental conditions. While plantar cutaneous afferents were blocked, important somatosensory information was still provided by the skin underlying the waist belt that suspended the subject before release. As noted before, ischemia induced at the ankle may block afferent as well as efferent innervation of the foot. Likewise, the tibial nerve accessible at the ankle joint contains cutaneous, muscular, articular, and vascular fibers which may be affected by injection of anesthetics. It is therefore impossible to isolate the normal role of plantar cutaneous afferents in the response to a sudden fall using this paradigm.

4. Research Design & Methods

The proposed project involves two experimental phases designed to test hypotheses regarding the role of plantar cutaneous afferents in normal balance control. The first phase involves quiet stance; the second phase is a study of balance during simulated slips. Ten healthy subjects will be used for each of the two phases. It is assumed that changes in stabilogram-diffusion (SD) parameters associated with altered plantar sensation will be similar in magnitude to those seen with differences in vision or aging. A power analysis using vision and aging data in the literature [17-19] suggests that at least seven subjects are required to demonstrate significant changes in this study. The number of subjects for Phase 2 was selected based upon a previous study of the effects of diabetic neuropathy on responses to similar support surface perturbation. In this study, nine patients with matched controls were sufficient to demonstrate significant differences [6]. Subjects will be selected according to the following criteria: a) ages between 18 and 50 years; b) no evidence or history of somatosensory, vestibular, or other neurologic, muscular, neuromuscular, gait, orthopedic, or postural disorder; c) no history of cardiac arrhythmia, sensitivity to lidocaine, or type I or type II diabetes. Each subject will provide informed consent before participating in the study. The experimental protocol have been reviewed and approved by the Boston University Institutional Review Board.

4.1 Experimental Phase I: Quiet Stance

Specific Aim 1: *Characterize the role of plantar cutaneous afferents in the maintenance of upright balance during quiet standing.*

4.1.1 Procedure for Experiment 1

The protocol for Experiment 1 is summarized in Table 4. Postural sway during quiet stance is evaluated using a Kistler 9284 multi-component force platform by recording the time-varying displacements of the resultant ground reaction force (center-of-pressure or COP). The static balance test battery consists of quiet stance while performing three different tasks. For each trial, subjects are instructed to stand upright on the force platform and

remain as still as possible. They receive verbal encouragement in this regard between each trial and are allowed to view the COP time series from the previous trial. During each trial, they assume a standardized stance in which the subject's feet are abducted 10 degrees and his/her heels are separated mediolaterally by a distance of 6 cm [17]. A removable jig has been constructed to ensure the precise placement of the feet before each trial. The subjects' hands are held at their sides. The quiet standing trials consist of four tasks, each task requiring ten 30s trials. In the first task, the subjects stand on two feet with their eyes open, while the second is performed with eyes closed. The third task consists of unipedal stance on their dominant foot with eyes open. The dorsal foot surface of the unweighted foot is held in contact with the calf of the stance leg. If the subject is forced to touch their non-dominant foot to the floor to maintain balance, the trial is repeated. In our experience, the unipedal stance task may require up to 13 attempts to produce ten complete 30s trials.

Each subject performs the aforementioned static balance test battery under three conditions comprising different levels of plantar cutaneous sensation: normal sensation (control), enhanced sensation, and reduced sensation. The control condition is performed as previously described. In the enhanced sensation condition, subjects perform the test battery while standing on a surface designed to increase pressure sensation from the foot sole. This surface consists of a smooth plate on which 2mm diameter steel balls have been affixed in a 5mm by 5mm staggered grid pattern. The pattern is arranged so that only the forefoot (distal to the base of the metatarsals) is in contact with the matrix, while the rearfoot is in contact with a smooth surface. Pilot testing suggests that the threshold for 2-point discrimination of pressure applied to the skin under the metatarsal heads may be as low as 8-10mm (using #5.07 Semmes-Weinstein monofilaments). This distance is far smaller than the 21mm previously reported for the "center of the sole" [68]. The spacing of the balls is designed to produce an increased sensation of pressure while preventing the perception of the grid pattern. We hypothesize that the increase in local pressure sensation in the skin contacting the balls will lead to an overestimation by the CNS of the total pressure impinging on the forefoot.

In the reduced sensation condition, subjects perform the same test battery after temporary anesthesia of portions of the foot sole. Anesthetic is applied by iontophoresis, a technique in which ionized anesthetic molecules are carried into the skin with a small applied electric current. Iontophoretic anesthesia specifically targets cutaneous sensation without affecting other afferents. In contrast, other methods such as ischemia, cooling, or nerve blocks will affect joint afferents as well as motor and proprioceptive functions of the intrinsic foot muscles. While not as effective as multiple percutaneous infiltrations, iontophoretic delivery has the added benefit of being painless with no risk of infection.

The plantar skin is prepared for iontophoresis by removing the most superficial layers of the stratum corneum using adhesive tape to reduce the impedance of the skin. The impedance is further reduced by soaking the feet in warm tap water for 20 minutes. A solution of 4% lidocaine HCL and 1:50,000 epinephrine is then iontophoretically delivered to the skin under the heads of the metatarsals of each foot (see Figure 3). A 1kHz pulsed DC current of 5mA is applied to four 6.5cm^2 IOGEL electrodes (Iomed Inc., Salt Lake City, UT) for approximately 80 minutes. Waveforms applied to adjacent electrode sites are out-of-phase so that no more than 5mA is applied to each foot at any instant. Cathodes for each circuit are placed over the calf muscles of the ipsilateral legs. The procedure is painless, with subjects only reporting a tingling sensation during the first few minutes of the application.

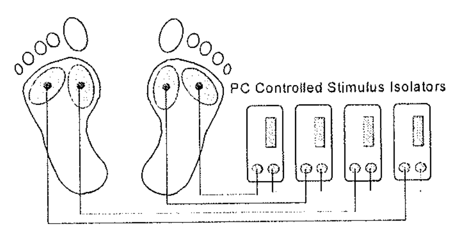

Figure 3: **Placement of Iontophoresis Electrodes.** Anodes (6.5cm^2) are placed over the first and between the third and fourth metatarsal heads. Cathodes are located over the ipsilateral gastrocnemius muscles.

The depth of anesthesia is assessed using a modified 2-alternative forced-choice assessment adapted from Holewski *et al.* (1988). The center of the anesthetized area is stimulated with a series of Semmes-Weinstein monofilaments (Stoelting Co., Wood Dale, IL). These filaments are designed to assess cutaneous pressure sensation and calibrated such that a specific force is required to make them buckle. In the Holewski paradigm, the experimenter counted "one . . . two", pressing a filament to the skin on either "one" or "two" in a randomized fashion. The subject was asked to report whether they felt pressure on "one" or "two" or if they could not differentiate between the two options. The experimenter tested each filament in a series of increasing stiffness, repeating the series three times at each site. The lowest stiffness at which the subject correctly identified the onset of pressure in at least two of three trials was designated the Sensitivity Threshold Level (STL) for that location [38]. In pilot studies using this paradigm, however, we found that the stiffer filaments tended to stick to the skin, causing an unpredictable vibration when withdrawn which seemed to produce a greater sensation than simple pressure. We therefore modified the Holewski paradigm so that the experimenter counts "one . . . two . . . three", pressing the skin on either "one" or "two" but always holding the filament on the skin until "three". Since the subject is asked to report only the *onset* of pressure, the vibratory sensation felt when pressure is removed does not affect the subject response. The duration of the anesthetic effect is of concern for this experiment due to the time required for balance testing. In order to reduce the time involved in testing the depth of anesthesia, the experimenter applies each filament three times in succession. Testing of a particular site on the footsole ends with the smallest diameter filament that can be identified correctly in at least two of three trials. Anesthesia is considered successful if the STL at each site increases to filament 5.07 (approximately 785kPa) or greater. This STL was found frequently at the metatarsal heads of diabetics suffering from foot ulcers (i.e. late stage DPN) but very rarely in non-diabetics [38]. STL's for each electrode site are assessed before and after anesthesia, an again after balance testing to document any degradation of the anesthetic effect.

In order to demonstrate that the iontophoretic anesthesia has no effect on muscle proprioceptors, a brief test of toe position perception is administered before and after anesthesia. The experimenter wiggles the second or fourth toe up and down rapidly, stopping randomly in the up or down position. The subject then identifies the position of the toe ("up" or "down") without seeing their feet. This procedure is repeated 10 times for each of the second and fourth toes, and any incorrect answers noted.

Table 4
Test battery for experiment 1 (Sensory conditions may be tested on different days)

Control Condition	Trial Dur	# Trials	**Reduced Pressure Sensation**	Trial Dur	# Trials
Bipedal, Eyes Closed, Distraction Task	30 s	10	Toe Proprioception Assesment		20
Bipedal, Eyes Closed, Still as possible	30 s	10	Pressure Sensation Assessment	8 min	
Bipedal, Eyes Open, Still as possible	30 s	10	Iontophoretic Anesthesia of footsole	80 min	
Unipedal, Eyes Open, Still as possible	30 s	10	Toe Proprioception Assesment		20
Enhanced Pressure Sensation	Trial Dur	# Trials	Pressure Sensation Assessment	8 min	
Bipedal, Eyes Closed, Distraction Task	30 s	10	Bipedal, Eyes Closed, Distraction Task	30 s	10
Bipedal, Eyes Closed, Still as possible	30 s	10	Bipedal, Eyes Closed, Still as possible	30 s	10
Bipedal, Eyes Open, Still as possible	30 s	10	Bipedal, Eyes Open, Still as possible	30 s	10
Unipedal, Eyes Open, Still as possible	30 s	10	Unipedal, Eyes Open, Still as possible	30 s	10

4.1.2 Analysis for Experiment 1

Analysis of quiet stance is performed using the stabilogram-diffusion method [17, 69-72]. Derived from statistical mechanics, this method involves the modeling of COP displacements during quiet stance as a quasi-random walk. Briefly, fractional (or fractal) Brownian motion is described by the equation

$$\langle \Delta r^2 \rangle \sim \Delta t^{2H}, \qquad (1)$$

where Δt is a time interval, $\langle \Delta r^2 \rangle$ the mean-squared displacement occurring over Δt, and H is the scaling coefficient. The autocorrelation coefficent in this case is given by $C = 2(2^{2H-1}-1)$. A scaling coefficient H greater than 0.5 signifies postively correlated behavior and is termed *persistence*; $H < 0.5$ describes negatively correlated behavior or *antipersistence*. As H increases, low frequency noise within a time series increases and produces excursions (drift) which are large in amplitude with respect to the high frequency components. In contrast, low values of H correspond to very noisy data, where low frequency excursions are of the same order of magnitude as local higher frequency noise [73]. A scaling coefficient of 0.5 produces an uncorrelated random walk and can be described by the equation

$$\langle \Delta r^2 \rangle = 2D\Delta t, \qquad (2)$$

where D is the diffusion coefficient. In order to describe stochastic activity in COP time series where $H \neq 0.5$, Collins & De Luca (1993) redefined D in equation (2) as the "effective diffusion" coefficient.

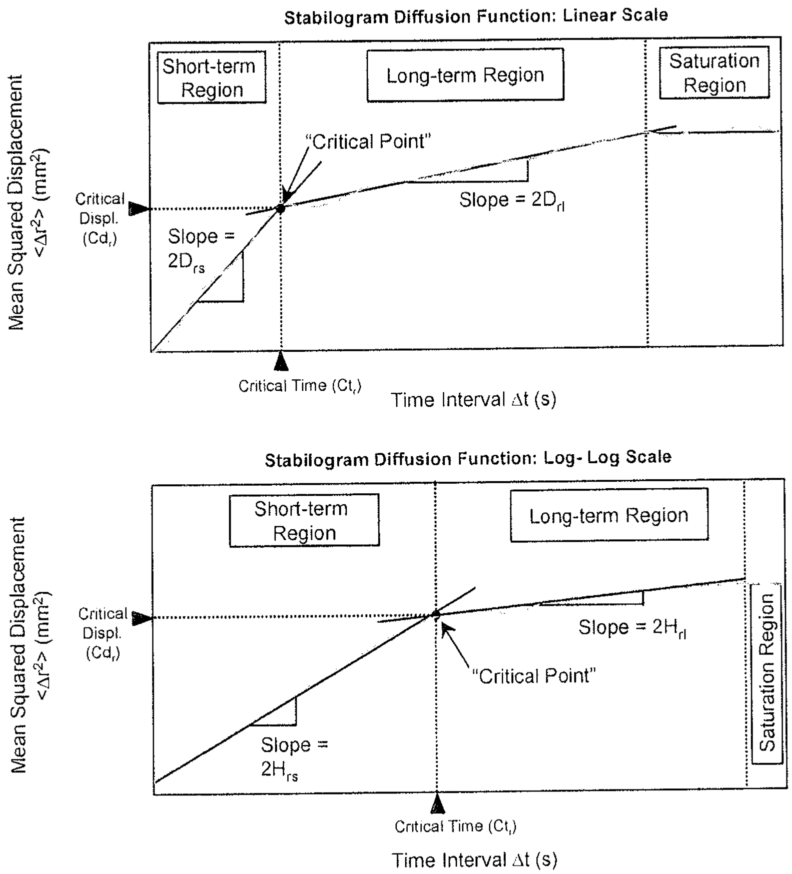

Figure 4
Stereotypical Form of the Stabilogram-Diffusion Function.
For a given time interval Δt,

$$\langle \Delta r^2 \rangle_{\Delta t} = \frac{\sum_{i=1}^{N-m} (\Delta r_i)^2}{(N-m)},$$

where N is the total number of samples, m is the number of samples encompassed by Δt, and r is the time dependent position of the COP in either the mediolateral (x) or anteroposterior (y) direction. In the current implementation, the critical point is defined as the point at which the SD function first becomes antipersistent; that is, where the slope of the log-log plot equals ½. The SD parameters are computed from the slopes of linear regressions fitting the short (t=0-Ct) and long term (Ct-10s) regions. The saturation region is typically not encountered in 30s trials of bipedal quiet stance.

The coefficients D and H are determined from the slopes of the linear and log-log plots of $\langle \Delta r^2 \rangle$ versus Δt, where r is the COP displacement in either the mediolateral or anteroposterior directions. Stabilogram-diffusion analysis of COP trajectories reveals two regions of behavior which can be described by different diffusion and scaling coefficients. The transition between these two regions is characterized by the *critical point* (see Figure 4). Appropriate selection of the critical point time interval coordinate, or *critical time*, is crucial to the calculation of meaningful stabilogram-diffusion coefficients because it determines the range of regressions.

Rather than locating the greatest change in slope, we have chosen the time interval at which the stabilogram-diffusion curve first crosses from persistence to antipersistence (H = 0) as the critical time. We believe our choice is more appropriate because it reflects the time interval at which the postural control system is able to arrest the persistent motion of the body. Collins and De Luca (1993) demonstrated that considerable variability may exist between the stabilogram-diffusion (SD) curves calculated from individual trials of quiet stance. Parameters extracted from the ensemble average of 10 SD curves were repeatable for a given subject, however, suggesting these parameters as a clinical description of performance. By characterizing the stochastic nature of postural sway over two different time scales (short term and long term regions), this method provides better insight into neural control mechanisms than traditional metrics, such as mean sway velocity or amplitude. Later studies demonstrated that SD parameters are useful for describing the reliance of subjects on visual feedback [18] as well as the effects of aging [19] and parkinsonism[20] on balance control. In this study, differences between diffusion parameters from the control and anesthetized conditions and between control and enhanced conditions are tested for statistical significance using the Wilcoxan Matched Pairs test for repeated measures.

In addition to stabilogram-diffusion parameters, a number of more traditional measures of COP activity are used in this study. Mean sway velocities, ranges and net path lengths are calculated under each condition and task. Because inter-trial changes in foot placement are minimized through the use of a non-compliant jig, we are also able to measure small shifts in the average location of the COP associated with the different tasks and sensory conditions.

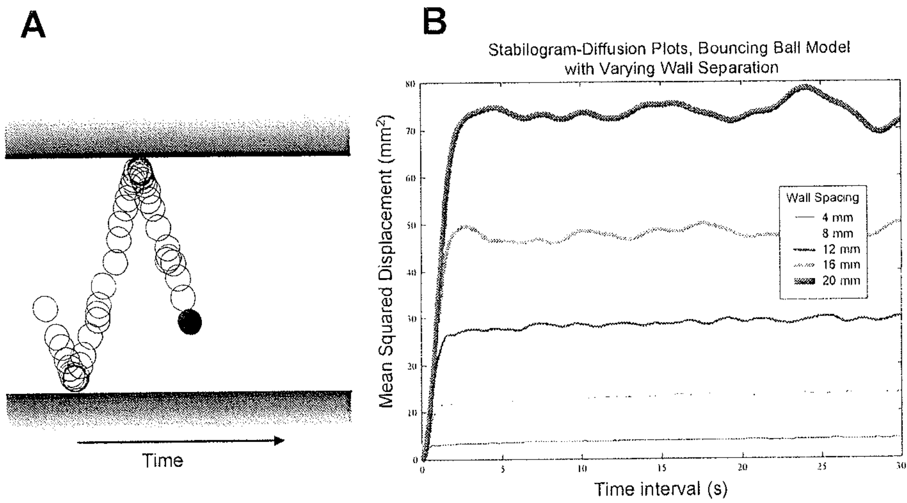

Figure 5. **Bouncing Ball model of COP displacements.** (A) Basic concept of bouncing ball model. The ball, representing the body COP, bounces between two fixed walls. Collisions with the walls represent the transient application of corrective ankle torques and are perfectly elastic. The position and velocity of the ball as well as the position of the walls are noisy. (B) Example SD plots showing the effect of increases in the average distance between the walls. Each curve is an average of 100 simulation trials. Increasing the distance between the walls increases slope in the short-term region and increases the critical time and displacement.

The first aim of the proposed project is to characterize the role of plantar cutaneous afferents in the control of quiet stance. Two simple models were developed to predict and explain the changes in SD parameters expected with an increase or decrease in plantar sensation. Collins and De Luca hypothesized that the persistent behavior seen in the short term region of the SD plot was indicative of open-loop control whereas the long term region described closed-loop feedback control [17, 71, 72]. Changes in sensory thresholds would then be expected to produce corresponding shifts in the SD critical point. Simulations were performed using a simple model of COP displacements in the form of a "noisy" ball bouncing between two walls. Collisions with the wall were perfectly elastic, representing a sudden postural correction. These simulations demonstrate that an increase in sensory threshold, modeled as an increase in the distance between walls, can be expected to increase critical time, critical displacement, and short-term diffusion coefficient. Isolated increases in sway velocity are predicted to produce a "ring" at the critical point, while increasing the variance of sway velocity will sharpen the corner at the critical point.

As an alternative to the open/closed loop postural control, Peterka (2000) recently proposed a continuous-feedback PID controller model which can produce SD plots similar to plots derived from real COP data [73]. Using this model, he was able to demonstrate the effect of changes in various model parameters on SD coefficients. While this model did not prove that the postural control system operated exclusively in closed-loop mode, it did suggest a viable alternative hypothesis for the existence of two linear regions in physiological SD curves. A potential failing of this otherwise excellent work is that baseline model parameters were chosen without regard to physiological data. For example, the proportionality constant used in Peterka's model appears to be far larger that the measured stiffness of the ankle joint [14, 15]. A second conceptual model of quiet stance being developed for our study is similar in form to Peterka's PID controller (see Figure 5). This state-space model, however, includes both passive control mechanisms (joint stiffness and damping) as well as active feedback. The major difference lies in the non-linear sensitivity of the active feedback, which includes a "deadzone" surrounded by a linear response. We believe that the experimental results from increasing and decreasing plantar sensory thresholds may be more simply explained by a simple expansion of the sensory deadzone rather than a coordinated change of several PID parameters.

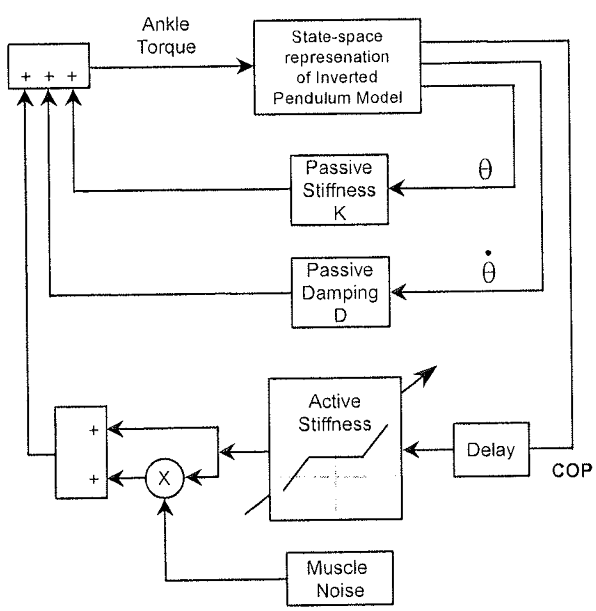

Figure 5: **Simplified State-Space Posture Model.** Passive ankle joint stiffness and damping provide instantaneous torque in response to changes in pendulum angle or angular velocity. In this simplified model, COP position is the only sensory feedback available to the posture control system. Active torque is represented by a non-linear response function that includes a central deadzone. The magnitude of the active response to COP within the deadzone is independent of COP position and may be modulated centrally based upon cognitive perception of task conditions. The minimum width of the deadzone is determined by the absolute sensory threshold for perception of COP changes, while the actual width of the deadzone is modulated by cognitive perception of task conditions. Noise added to the system by random fluctuations in muscle force output is proportional to the intended active stiffness. The delay in active response to COP changes is on the order of 100ms.

4.2 Experimental Phase 2: Simulated Slips

Specific Aim 2: *Characterize the role of plantar cutaneous afferents in the maintenance of upright balance during simulated slips.*

4.2.1 Procedure for Experiment 2

Experiment 2 involves the acquisition of information related to the postural responses to simulated slips. Slipping conditions are simulated by horizontal support surface translations in the anterior and posterior directions. These perturbations will be performed using BALDER (BALance DisturbER), a computer-controlled moving platform installed in the Injury Prevention & Analysis Laboratory of the NeuroMuscular Research Center. The BALDER platform measures 2.2m x 2.2m, with an AMTI (Newton, MA) ORG6-3 triaxial force plate flush-mounted in the center.

During each perturbation, the BALDER control computer will acquire ground reaction forces and moments from the force plate during the perturbations and ensuing recovery. A second system will collect

electromyographic data (EMG) from muscles involved in recovery of balance after backward translation of the support surface: soleus, biceps femoris, rectus abdominus, and rectus femoris. The EMG electrodes and amplifier used in this experiment have been modified especially for use in the high-electromagnetic noise environment surrounding the BALDER platform. While both forward and backward perturbations are performed in this experiment, acquisition of EMG is currently limited to four muscles due to the limitations of this custom hardware. We have therefore elected to only monitor muscle activity during backward perturbations. Joint kinematics will be collected using an Optotrak 3010 (Northern Digital, Waterloo, ON) infrared motion analysis system. Infrared diodes will be fixed to joints visible in the sagittal plane: the ankle at the maleolus, knee at the femoral epicondyle, hip at the greater trochanter, shoulder at the acromium process, and head at the zygomatic arch. Two markers will be fixed to the platform as well. Kinematics will be acquired at 100Hz; EMG and kinetics will be sampled at 1kHz. All data acquisition systems will be synchronized to maintain a uniform time base.

Support surface translations will be 15cm in length with a peak velocity of 60 cm/s. Nine different accelerations (2, 3, 4, 5, 6, 7, 8, 9, and $10 m/s^2$) will be tested in two directions (forward and backward). These parameters were selected so that the transition from pure ankle strategy to hip strategy can be documented as a function of acceleration. The 18 possible combinations applied in random order form a block of trials; subjects will undergo five blocks so that each condition is repeated five times. Subjects will be exposed to an initial block of perturbations before data collection begins to eliminate the startle reflexes typically seen in the first few trials. Perturbations will be applied in a random order, however, so subjects will remain naive to the acceleration and direction of the perturbation.

Participants will first experience these balance perturbations under normal sensory conditions. They will then repeat the battery while plantar cutaneous sensation is enhanced, and again when it is reduced by the methods employed in Experiment 1. A summary of the test battery for Experiment 2 is provided in Table 5.

Table 5
Test battery for experiment 2 (Sensory conditions may be tested on different days)

Control Condition	# Fwd Perturb	# Bwd Perturb	**Reduced Pressure Sensation**	Duration	#Trials
Perturbation Block 1	9	9	Toe Proprioception Assesment		20
Perturbation Block 2	9	9	Pressure Sensation Assessment	8 min	
Perturbation Block 3	9	9	Iontophoretic Anesthesia of footsole	80 min	
Perturbation Block 4	9	9	Toe Proprioception Assesment	8 min	
Perturbation Block 5	9	9	Pressure Sensation Assessment		20
Enhanced Pressure Sensation	# Fwd Perturb	# Bwd Perturb		# Fwd Perturb	# Bwd Perturb
Perturbation Block 3	9	9	Perturbation Block 2	9	9
Perturbation Block 4	9	9	Perturbation Block 1	9	9
Perturbation Block 1	9	9	Perturbation Block 5	9	9
Perturbation Block 5	9	9	Perturbation Block 3	9	9
Perturbation Block 2	9	9	Perturbation Block 4	9	9

4.2.2 Analysis for Experiment 2

Analysis of data from experiment 2 will include the calculation of muscle response latencies and characterization of responses in terms of ankle or hip strategies. Latencies of muscle activation will be determined from EMG collected during backward translations of the support surface. Onset of muscle activity

will be defined as the first sample at which the RMS EMG amplitude exceeds twice the baseline standard deviation (as collected in the 200ms before platform movement) for longer than 25ms. Results of this automated procedure will be checked visually. Differences in muscle latencies between the sensory conditions will be tested for statistical significance using an appropriate test for repeated measures.

Postural response strategies will be characterized in terms of net joint torques at the ankle, knee, and hip. Net joint torques for each trial will first be estimated using a variation of the linear quadratic follower method [74]. This method calculates net joint torques by creating a forward simulation that reproduces observed kinematic (joint angles) and ground reaction force data. Specifically, it employs a four segment sagittal plane model of the subject standing on the moving platform (see Figure 6) The equations of motion that describe the model are linearized about an upright posture to produce a state-space representation. The goal is then to produce net joint torque estimates at the ankle, knee, and hip which are both physiologically reasonable and produce kinematic estimates that closely match the observed data. This is accomplished through the minimization of the cost function

$$J=\frac{1}{2}e_0^T S_0 e_0+\frac{1}{2}e_f^T S_f e_f+\frac{1}{2}\int_{t_0}^{t_f}(e^T Q e+u^T R u)dt \qquad (3)$$

where e are the errors between simulated and measured kinematics, e_0 and e_f are the initial and final states of this error, u are the net joint torques, and S_0, S_f, Q, and R are weighting matrices. Inverse dynamic methods that do not account for the implicit trade-off between plausibility of joint torque estimates and accuracy in feed-forward kinematic estimates can result in perfect re-creation of the measured kinematics while producing non-physiological joint torque estimates. Previous studies using the linear quadratic follower technique on postural perturbation data have produced reasonable torque estimates that reproduce kinematic and kinetic data to within +/-1° and +/-10Nm respectively [23].

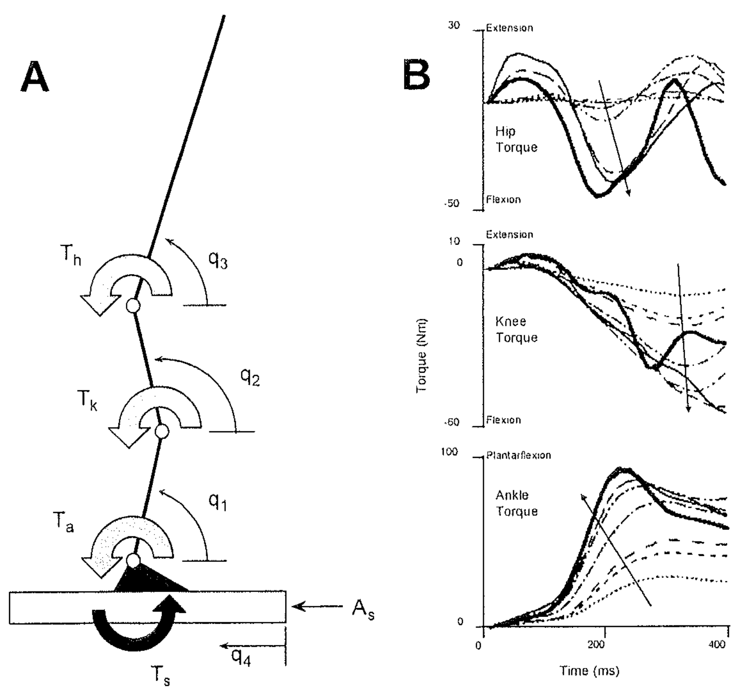

Figure 6: **Four segment sagittal plane model of the human body with example joint torque estimates.** (A) Four segment model. Segment angles are defined with respect to the horizontal and measured experimentally. Support surface torque T_s and applied linear acceleration are also measured experimentally. Net joint torques at hip (T_h), knee (T_k), and ankle (T_a) are estimated using the linear quadratic follower method. (B) Example net joint torque estimates from Runge *et al.* (1999). Arrows indicate trends associated with increasing peak support surface translation velocities. While ankle and knee torques appear to retain their general shapes, a biphasic hip torque appears to emerge as velocity increases. This characteristic change in hip torque profile is indicative of the use of a hip strategy to counter the perturbation.

In the current study, the use of a hip strategy during postural perturbations will be identified for each subject based upon the emergence of a well defined biphasic hip torque pattern that is absent at during low-acceleration perturbations [22]. Changes in the acceleration at which the hip torque becomes biphasic due to increased or decreased plantar sensation will be evaluated. The magnitude and timing of peak joint torques will also be compared between different sensory conditions using the Wilcoxon matched pairs test. In addition, subject-

independent motor patterns for each perturbation acceleration will be created using Karhunen-Louve expansion of average joint torques from each subject [75]. Runge *et al.* (1998) demonstrated that the principal eigenvector was sufficient to represent subject-independent joint torques in response to backward perturbations [22]. These subject independent torque patterns will be compared between plantar sensation conditions in order to determine if changes in joint torque profiles are consistent across subjects.

5. Preliminary Results

Data was collected from three healthy adults (2 male, 1 female) according to the methods described for Experiment 1. The "stand as still as possible" task used in these experiments represents a functional performance limit of the postural control system. The "gain" of vestibular, visual, and somatosensory feedback systems are expected to be maximized during this task. There is therefore a possibility that while foot sole afferent information may be important during normal stance, compensation by other afferent systems during the "stand as still as possible" task could mask this importance. We therefore collected data from an additional four healthy adults (2 males, 2 females) in an identical manner except these subjects were asked to stand quietly while listening to a murder-mystery novel on audio tape. This task was intended to distract the subjects such that their mental concentration on balance control was both similar to everyday quiet stance and repeatable between trials. The distinct disadvantage of this technique is that inter-trial variation is far larger than seen using the "stand as still as possible" technique. The literature, however, suggests that ten 30 second trials of "quiet stance" are sufficiently repeatable to provide meaningful SD parameters [17]. Since no consistent differences were found between the "still as possible" and distracted subjects, the two groups are pooled in our preliminary analyses.

Table 6

Notable Changes in Stabilogram Diffusion Parameters With Respect to Control Condition

Bipedal, Eyes Open

Anesthesia		
Parameter	Median Change	p value
D_{ys}	-18%	0.043
D_{xl}	46%	0.091

Enhanced		
Parameter	Median Change	p value
H_{xs}	2%	0.063
Ct_y	16%	0.063
Cd_y	71%	0.043

Bipedal, Eyes Closed

Anesthesia		
Parameter	Median Change	p value
D_{ys}	-18%	0.063
H_{ys}	-3%	0.063
H_{yl}	113%	0.063

Enhanced		
Parameter	Median Change	p value
D_{xs}	19%	0.018
H_{xs}	3%	0.018
Cd_x	32%	0.063

Unipedal, Eyes Open

Anesthesia		
Parameter	Median Change	p value
D_{yl}	29%	0.091

Enhanced		
Parameter	Median Change	p value
D_{yl}	18%	0.063
H_{xl}	-42%	0.063

X & y denote lateral and anteroposterior planes respectively.
change.
Highlighted items are discussed in the text

Table 7

Notable Changes in COP Statistics With Respect to Control Condition

Bipedal, Eyes Open

Anesthesia		
Statistic	Mean Change	p value
Inter-trial Var of COP_x Means	8.59 mm^2	0.043

Enhanced		
Statistic	Mean Change	p value
Mean COP_y	1.59 mm	0.008
Inter-trial Mean of Intra-trial COP_y Variance	1.62 mm^2 *	0.069

Bipedal, Eyes Closed

Anesthesia		
Statistic	Mean Change	p value
Mean COP_y	-3.34 mm	0.062
Inter-trial Var of COP_x Means	7.80 mm^2	0.025
Inter-trial Var of COP_y Means	18.54 mm^2	0.044

Enhanced		
Statistic	Mean Change	p value
Inter-trial Var of COP_x Means	6.41 mm^2	0.03

Unipedal, Eyes Open

Anesthesia		
Statistic	Mean Change	p value
Inter-trial Var of COP_x Means	2.64 mm^2	0.028

Enhanced		
Statistic	Mean Change	p value
Inter-trial Var of COP_y Means	-7.47 mm^2	0.054
COP_x Range	1.89 mm *	0.063

X & y denote lateral and anteroposterior planes respectively. * Median change rather than mean

Highlighted items are discussed in the text

Table 6 depicts notable changes in SD parameters associated with manipulations of foot sole sensation. Of particular interest are the changes seen when the subjects' eyes are closed in bipedal stance. Hypothesis 1 predicted that anesthesia of the foot sole would increase the COP deviation experienced before a correction is made. This change in response threshold would increase the short-term diffusion coefficients, critical times, and

critical displacements. In terms of the Bouncing Ball model, Hypothesis 1 predicted that reduced plantar sensation would increase the distance between the walls, thereby increasing the time and displacement of the ball between collisions (i.e. postural corrections). Stochastic activity of the ball near the walls is constrained by the boundary; an increase in the distance between walls would increase the total amount of stochastic activity between collisions.

While only preliminary, the data suggest an alternative interpretation of the effect of anesthesia on the Bouncing Ball model. Rather than increasing the net spacing between the walls, anesthesia may add low frequency noise to the position of the walls (see Figure 7). Physiologically, this corresponds to increased drift in the location of the postural "set point" or reference position. The average position of the COP can be considered a rough approximation of this reference position. The alternative hypothesis is then supported by findings of both a net shift in average COP position and an increase in the inter-trial variability of this reference position (see Table 7). In addition, the long-term scaling exponent (AP direction) is doubled, indicating low frequency drift in the balance control system. The decreases in short-term diffusion coefficient and scaling exponent may be explained by decreased corrective torque amplitudes due to reduced perception of foot pressure. Likewise, the increase in short-term diffusion coefficient, scaling exponent, and critical displacement associated with enhanced pressure sensation may be due to an increase in the amplitude of postural corrections.

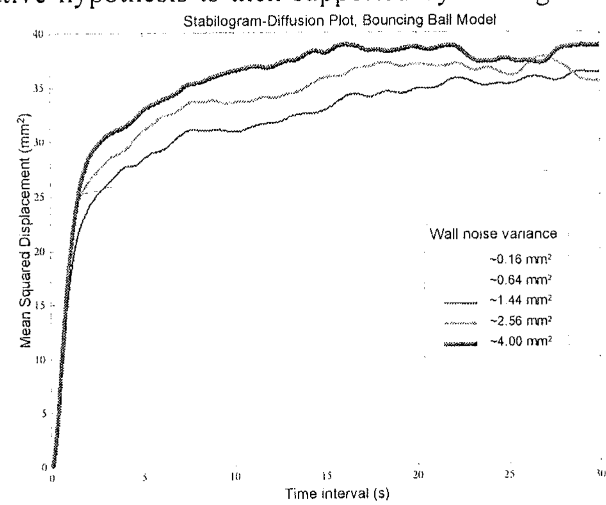

Figure 7: **Example of the effect of wall position drift on the Bouncing Ball model.** The positions of the walls are subject to bandlimited (.5Hz) Gaussian noise. Increasing noise variance leads to increased slope of the SD function in the long term region. Here the mean ball velocity is 5mm/s and the mean distance between the walls is 12mm. Each curve is an average of 100 trials.

The preliminary results from Experiment 1 demonstrate the effectiveness of the iontophoretic anesthesia procedure for reducing foot sole sensation and eliciting meaningful changes in balance control. Based upon this success, data will be collected from an additional seven subjects standing "still as possible" according to the procedures previously described. The expansion of the subject pool to ten subjects performing identical tasks will greatly enhance the statistical power of the study.

6. Conclusion

Epidemiological evidence indicates that peripheral sensory neuropathies are strongly associated with balance dysfunction and related injuries. Studies of both healthy subjects and DPN patients have demonstrated a link between reduced somatosensation from the foot and ankle and reduced stability during quiet or perturbed stance. To this date, however, no study has successfully isolated the role of plantar sole cutaneous mechanoreceptors in normal balance control. Our preliminary results from Experiment 1 demonstrate a novel technique to selectively manipulate foot sole sensation. This technique produces meaningful changes in balance control that allow us to investigate the specific role of foot sole mechanoreceptors. Quantification of these changes using a statistical mechanics approach provides insight into balance control behavior over multiple time scales. Together with traditional measures of posture control, these data can be used to draw conclusions regarding the sensorimotor integration of information derived from foot sole afferents. Experiment 2 will

expand the study to include an investigation of subject responses to simulated slips, perturbations far larger than the unconscious movements produced during quiet stance. The manipulation of foot sole sensation during these large perturbations is expected to provide a greater understanding of the role of foot sole afferents in preventing falls. Experiments 1 and 2 together form a cohesive, novel investigation which will provide important insight into the cause and prevention of fall related injuries associated with peripheral sensory neuropathy.

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protocol tables.xls Computer file dated 12/14/2000

Tab: Test 1

Test 1: ___________ **Normals**		# Trials	Time reqd	Analysis
Set 1	Quiet stance 2 feet (EO), Motion analysis	10	30 min	Stabilogram-Diffusion, EIP behavior
Set 2	Quiet stance 2 feet (EC), Motion analysis	10	20 min	Stabilogram-Diffusion, EIP behavior
Set 3	Quiet stance 1 foot (EO), Motion analysis	10	20 min	Stabilogram-Diffusion, EIP behavior
	Iontophoresis of footsole		2.5 hr	Sensory loss via filaments
Set 4	Ankle inversion/eversion threshold	20	30 min	Average
Set 5	Quiet stance 2 feet (EC), Motion analysis	10	20 min	Stabilogram-Diffusion, EIP behavior
Set 6	Quiet stance 1 foot (EO), Motion analysis	10	20 min	Stabilogram-Diffusion, EIP behavior

Test 2: _________ **Normals**		# Trials	Time reqd	Analysis
Set 1	Simulated slips w/ Motion Analysis	40	1 hr	EMG response time, response "strategy"
	Iontophoresis of footsole		2.5 hr	Sensory loss via filaments
Set 2	Simulated slips w/ Motion Analysis	40	1 hr	EMG response time, response "strategy"

Test 3: ________ Vestibular Patients		# Trials	Time reqd	Analysis
Set 1	Quiet stance 2 feet (EO), Motion analysis	10	30 min	Stabilogram-Diffusion, EIP behavior
Set 2	Simulated slips w/ Motion Analysis	40	1 hr	EMG response time, response "strategy"
	Iontophoresis of footsole		2.5 hr	Sensory loss via filaments
Set 3	Quiet stance 2 feet (EO), Motion analysis	10	30 min	Stabilogram-Diffusion, EIP behavior
Set 4	Simulated slips w/ Motion Analysis	40	1 hr	EMG response time, response "strategy"

Test 4: _______ Normals		# Trials	Time reqd	Analysis
	Prosthetic training: walking around		1 day	
Set 1	Quiet stance 2 feet (EO), Motion analysis, prosthetic (?)	10	30 min	Stabilogram-Diffusion, EIP behavior
Set 2	Simulated slips w/ Motion Analysis, prosthetic (?)	40	1 hr	EMG response time, response "strategy"
	Iontophoresis of footsole		2.5 hr	Sensory loss via filaments
Set 3	Quiet stance 2 feet (EO), Motion analysis, prosthetic	10	30 min	Stabilogram-Diffusion, EIP behavior
Set 4	Simulated slips w/ Motion Analysis, prosthetic	40	1 hr	EMG response time, response "strategy"

Test 5: ________ Peripheral Neuropathy Patients		# Trials	Time reqd	Analysis
Set 1	Quiet stance 2 feet (EO), Motion analysis, prosthetic (?)	10	30 min	Stabilogram-Diffusion, EIP behavior
Set 2	Simulated slips w/ Motion Analysis, prosthetic (?)	40	1 hr	EMG response time, response "strategy"
	Prosthetic training: walking around		1 day	
Set 3	Quiet stance 2 feet (EO), Motion analysis, prosthetic	10	30 min	Stabilogram-Diffusion, EIP behavior
Set 4	Simulated slips w/ Motion Analysis, prosthetic	40	1 hr	EMG response time, response "strategy"

Exhibit K

Effects of Dipfoot Device, feedback on one leg only 10 SUBJECTS

p<.05 p<.005

Bipedal EC Change

	Dxs	Dys	Drs	Dxl	Dyl	Drl
Mean	22%	28%	24%	107%	-56%	-42%
	Hxs	**Hys**	**Hrs**	**Hxl**	**Hyl**	**Hrl**
	0%	-2%	-1%	62%	-59%	-43%
	Ctx	**Cty**	**Ctr**	**Cdx**	**Cdy**	**Cdr**
	-6%	-4%	-4%	16%	20%	18%

w/fb trials alternated

	Dxs	Dys	Drs	Dxl	Dyl	Drl
Median	31%	19%	16%	9%	-73%	-55%
	Hxs	**Hys**	**Hrs**	**Hxl**	**Hyl**	**Hrl**
	0%	-2%	-1%	-16%	-70%	-49%
	Ctx	**Cty**	**Ctr**	**Cdx**	**Cdy**	**Cdr**
	-7%	-7%	-5%	22%	8%	8%

Unipedal EO Change

	Dxs	Dys	Drs	Dxl	Dyl	Drl
Mean	9%	39%	32%	-9%	-29%	-26%
	Hxs	**Hys**	**Hrs**	**Hxl**	**Hyl**	**Hrl**
	-1%	2%	1%	-11%	-32%	-28%
	Ctx	**Cty**	**Ctr**	**Cdx**	**Cdy**	**Cdr**
	-7%	9%	-7%	11%	18%	14%

	Dxs	Dys	Drs	Dxl	Dyl	Drl
Median	19%	46%	34%	-9%	-25%	-21%
	Hxs	**Hys**	**Hrs**	**Hxl**	**Hyl**	**Hrl**
	0%	2%	1%	-12%	-23%	-21%
	Ctx	**Cty**	**Ctr**	**Cdx**	**Cdy**	**Cdr**
	-6%	-11%	-9%	11%	27%	19%

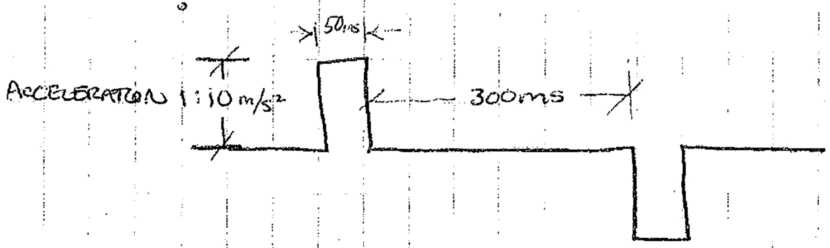
FURTHER STUDY REQUIRES A PLACEBO CONDITION - ACTUALLY 2

- VIBRATION IS PROVIDED @ RANDOM TIME & PLACE & MAGNITUDE   is this worth doing?
- VIBRATION IS PROVIDED @ RANDOM LOCATION, BUT AT APPROPRIATE TIME & MAGNITUDE

SHOULD THESE BE MIXED? MIGHT RUIN ADAPTATION.

BAUDER:

- Accelerometer on foot is very similar to one on platform



Accel/Decel Peak Vel Distance

Accel/Decel (cm/s^2)	Peak Vel (cm/s)	Distance (cm)
100	5	1.75
200	10	3.50
300	15	5.25
400	20	7.00
500	25	8.75
600	30	10.50
700	35	12.25
800	40	14.00
900	45	15.75
1000	50	17.50

McCall, Layne Blumberg - Check out NASA abstracts

1/23/2001

A Prosthetic Foot Sole for the Mitigation of Balance Deficits Caused by Reduced Plantar Sensation

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Purpose: Several million Americans suffer from peripheral sensory neuropathies, including a significant percentage of the elderly population. The consequent reduction in sensation from the feet and ankles has been linked to a number of balance deficiencies, including a significant increase in the risk of fall-related injuries during stance and ambulation. Conversely, astronauts exhibit increased sensitivity of the cutaneous foot sole after prolonged exposure to microgravity. This hypersensitivity may contribute to the balance impairments encountered by astronauts upon return to terrestrial gravity. The current project is a quantitative study of the specific role played by plantar cutaneous sensation in both static and dynamic balance control. Furthermore, this project includes the evaluation of a "prosthetic foot sole" sensory-substitution system intended to correct balance deficits associated with plantar sensory loss.

Methodology: Plantar cutaneous sensation is reduced by iontophoretic delivery of anesthesia, leaving foot and ankle proprioception and motor function unaffected. Increased plantar cutaneous sensation is achieved using an irregular support surface. In one experiment, the effects of reduced or increased plantar sensation on quiet stance are quantified using both traditional center-of-pressure measures and statistical mechanics techniques. A second experiment investigates the effect of plantar cutaneous sensation on automatic postural responses following support surface translations. The effects of reduced or enhanced plantar pressure sensation are then quantified by changes in net joint torque profiles and muscle activation patterns. The third portion of this project is an evaluation of a prototype "prosthetic foot sole" for the mitigation of balance deficits caused by reduced plantar sensation. This preliminary study involves the testing of the sensory-substitution device on normal subjects during quiet stance and simulated slipping conditions. Efficacy of the device will be determined by its ability to produce effects opposite those previously seen in subjects with reduced plantar sensation. The Boston University Institutional Review Board has approved all experiments associated with this project.

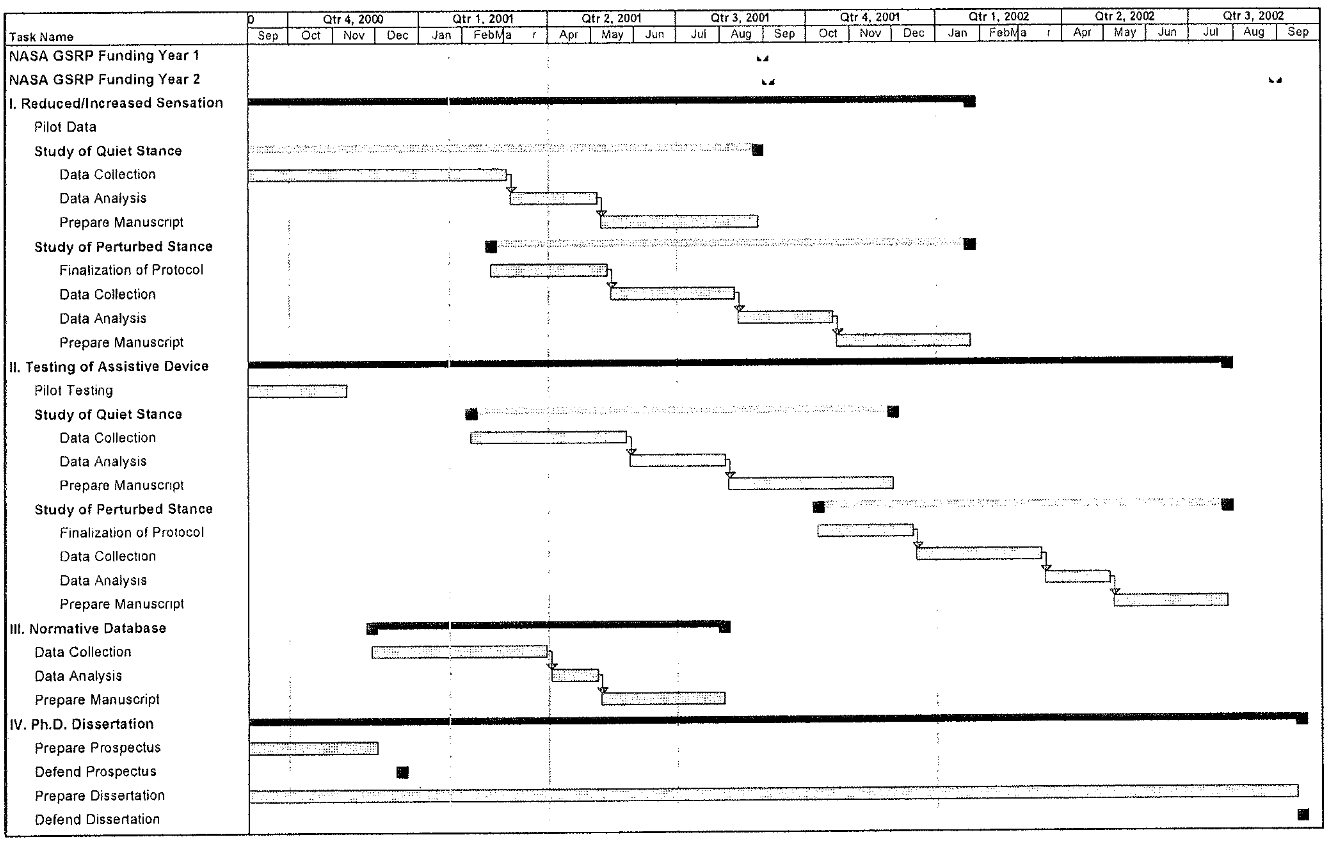
Progress: Quiet stance data has been collected and analyzed for seven subjects under normal, reduced, and enhanced plantar sensation conditions. Subjects were tested with and without vision as well as in bipedal and unipedal stance. In addition, ten healthy subjects were tested during quiet stance with and without the use of the prosthetic foot sole. To improve our interpretation of changes measured in these experiments, a normative study of the day-to-day variability in postural parameters has also been initiated. This work has led to a successful public defense of Mr. Meyer's Biomedical Engineering doctoral dissertation prospectus.

Results: Preliminary analyses indicate that a reduction in plantar sensation from the forefoot results in a large increase in low-frequency anterior-posterior drift of the center-of-pressure. This suggests an inability to maintain a stable postural "set position", a conclusion supported by a significantly increased variance in the mean position of the center-of-pressure between 30 second trials. Pilot testing of the sensory prosthetic on healthy subjects after only ~5 minutes of training demonstrated a significant reduction in low-frequency drift of the center of pressure. This result suggests that the prototype device may be useful for improving static balance control.

Future Work: Balance parameters from three additional subjects will be analyzed during quiet stance with normal, increased, and decreased plantar pressure sensation. Automatic postural responses to support surface translations will be studied in ten healthy subjects with temporary anesthesia of the foot soles.

Testing of the foot-sole prosthetic will continue with a comparison of the effects of balance-related and purely random feedback during quiet stance. This experiment will determine if a simple increase in cognitive attention can explain the decreases in low-frequency sway found using balance-related feedback. A study of the ability of this device to modify automatic postural responses to simulated slips will be performed. The normative study of day-to-day variability in postural parameters will be completed, involving ten subjects under both eyes open and eyes closed conditions. The results of the quiet standing experiment involving increased and reduced plantar sensation will be submitted for presentation at the Annual Meeting of the Society for Neuroscience in November 2001.

Estimated Project Schedule



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Professor of Biomedical Engineering
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July 9, 2001

Mr. Eilert Klatte
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Bremen, Germany 28279

Dear Mr. Klatte:

On behalf of the NeuroMuscular Research Center, I would like to offer you a Visiting Research Assistant position in the Injury Analysis and Prevention Laboratory for a period of six months. This position is made available to you with the understanding that you are able to acquire the necessary funds for this position through sources for which you are in the process of applying. We believe that you will find the experience to be invaluable to your career.

You will work in the Injury Analysis and Prevention Laboratory under the direction Dr. Lars Oddsson where you will be exposed to our biomedical research techniques and activities. Your specific project will involve the design of a foot pressure sensory substitution device to be used by patients with peripheral neuropathies. A functional prototype of the device has previously been completed as part of a recent Masters Thesis project in the lab. Your main responsibility will be to transform the prototype system into a portable one suitable for use in field-testing.

You will be expected to show initiative and independence in your research. Should you require more information regarding the details of this arrangement, please contact Dr. Oddsson directly.

If you agree to the terms of this appointment, please return a formal letter of acceptance as soon as possible.

The staff of the NeuroMuscular Research Center joins me in welcoming you to our facility. We look forward to a mutually rewarding relationship.

With best wishes,

Sincerely,

Carlo J. De Luca

cc: Dr. Lars Oddsson

Design and Test of a Foot Pressure Sensory Substitution Device

Individuals with peripheral neuropathies, commonly caused by diabetes, gradually lose their foot pressure sensation, which leads to increased risk of balance loss, and slip and fall related injuries. The aim of the current project is to design and build a second-generation prototype of a foot pressure sensory substitution device to be used by patients with peripheral neuropathies. The currently existing prototype device, built as part of a recent Masters Thesis project, can only be used in a lab based setting. An important goal of this project is to transform the prototype system into a portable one suitable for use in field-testing. The device uses pressure sensors arranged in an array to measure foot pressure under each foot. A microprocessor calculates specific parameters based on the pressure signals that are used to activate a set of vibrators through a D/A converter. The project includes both software and hardware design and implementation. The work will be performed in the Injury Analysis and Prevention Laboratory at the NeuroMuscular Research Center under the direction Dr. Lars Oddsson and Mr. Peter Meyer.

Exhibit O

DESIGN OF A MOBILE ARTIFICIAL SENSORY SYSTEM FOR FEET

INTERNSHIP PROJECT
SEPTEMBER 2001 – FEBRUARY 2002

BY

EILERT KLATTE

Abstract

For the human postural control system the pressure sensation from the soles of the feet provides important information. Diabetes mellitus often results in peripheral neuropathies that impair this sensation by degrading the peripheral sensory system.
The design of a mobile artificial sensory system for feet is an additional project, based on the prototype system from Mats Freding. He finished his master thesis project in March 2001 and the device is still in use on subjects in the injury analysis lab.
Feet sensors with electronic, stimulus feedback and a real time controlling of the parts together are the three major parts of this project. In use it is continually collecting pressure information under a subject's feet and then processing the data so that it can be logical skin. A secure feedback to the subject is realized through a vibratory stimulus. 12 vibrators were placed around each leg to stimulate the pressure sensation from the feet.
Unfortunately is the actual design of the device totally PC-Based with a data acquisition card (DAQ). The reasons for the decision to develop a PC-Based system had been the easier assembly of the electronics, the available resources with an existing PC and DAQ-Card in the lab and the more comfortable way to program it.
The goal is it to integrate the complete system into a "black box" with the sensor-input unit, a microcontroller, the vibrator output unit and a power supply. Depending of the force distribution measured by the seven sensors under the feet, the microcontroller calculates the direction and amplitude of the vibratory feedback. The deviation from the formerly calibrated mean is responsible for the vibratory output.
Varying from Mats Fredig project it is planed to increase the feedback to the subject. This would be realized by using three levels of vibrators for every leg. These levels allow it to give a force feedback of the pressure intensity to the subject during gait.
In a later, more commercial orientated version of the device it is necessary to integrate a foot-specific arrangement of the foot-sensors into the soles. The electronics box can be attached to a belt and the vibrators can be fixed through a kind of sock at the leg.
It was necessary to develop a new circuit design for the device. The actual design is implemented on two veloboards, which are mounted on top of each other to become an as small as possible surface. Through a "Zero Force Socket" is it fast, easy and secure possible to remove the microcontroller from the device. This is necessary to program the microcontroller with the specific weight constant of the subject.

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1 Goals and Objectives

The goals of the proposed project are to design and build a mobile device that may substitute sensory information from the feet during gait. Data acquisition and signal processing should be achieved to provide a proper feedback. This includes both real-time feedback, collecting pressure information from the feet and at a certain time with a proper computation make a feedback to the body. There are numerous components in the project to be looked into what was done by reading the manual and a evaluation of cost effectiveness and reliability.
It was necessary to design a new hardware layout to integrate a microcontroller and the software was programmed totally new in assembler.

2 Introduction

Problems with gait and balance function due to loss of sensory information following disease, injury or increased age is a common problem in our society today. Pressure sensation from the soles of the feet provides important information to the human postural control system. In patients over the age of 60, diabetes mellitus often results in peripheral neuropathies that impair this sensation by degrading the peripheral neuropathies. These patients may exhibit postural control deficiencies and an increased risk of falling. The question is if the sensory pressure information from the feet can be replaced by a sensory information substitution, a feedback system, to restore balance during gait to those suffering from peripheral neuropathies.
The design of a mobile artificial sensory system for feet is an additional project, based on a prototype system which is used in the NMRC. Unfortunately was this device designed to work with a data acquisition card (DAQ) in a totally PC-Based environment. The reasons for the decision to develop a PC-Based system had been the easier assembly of the electronics, the available resources with an existing PC and DAQ-Card in the lab and the more comfortable way to program it. But there was still the restriction that it was not possible to do very important experiments during gait.
The main components in this project are the 7 force sensing resistors (FSR) at the foot, the power supply, the complete data acquisition (DAQ) through the microcontroller in the "black box", the signal amplification and the feedback system through the 12 vibrators (see Figure 1).
A microcontroller is a cheap, small, fast and flexible solution to replace the PC-based DAQ-card. The selected PIC-Microcontroller has the big advantage, that there is a debugging system available to test the prototype devices. Eight analog inputs are directly supported on the microcontroller, so that the 7 FSR's can be connected without any further A/D conversion. The programmed code can be stored very comfortable in a "Flash" memory on the chip.
The microcontroller is based on a "Zero-Force" socket, so that he can be easy removed and programmed on an external device.

Each vibrator can be single addressed through the microcontroller and there are 16 steps of intensity through the D/A conversion possible.
A power supply with 12 rechargeable NiMH batteries is placed on the boards.
The extensive design makes it necessary to use two circuit-boards which are sandwich assembled in a box with an easy access to the components.

3 Hardware Design

The main components in this project are the 7 force sensing resistors (FSR) at the foot, the power supply, the complete data acquisition (DAQ) through the microcontroller in the "black box", the signal amplification and the feedback system through the 12 vibrators (see Figure 1).
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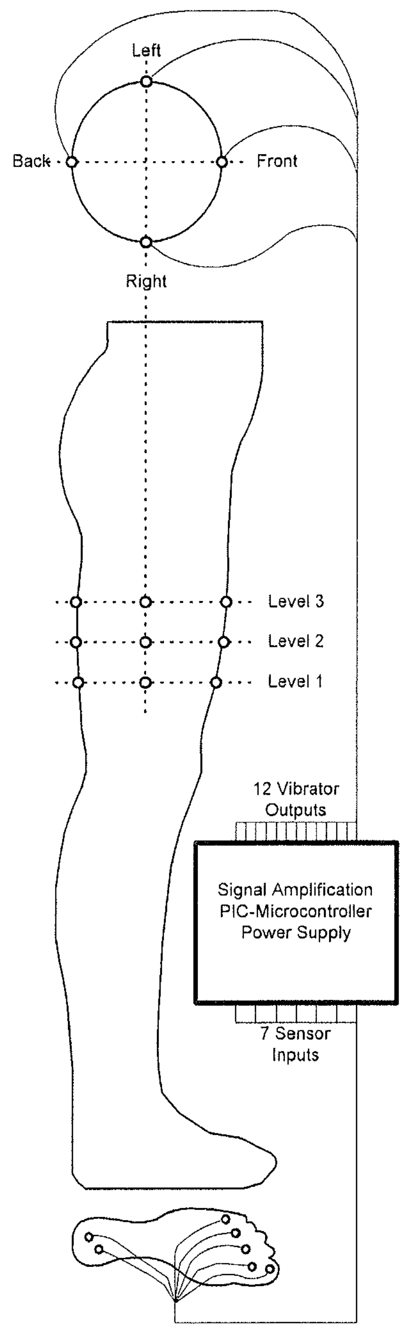
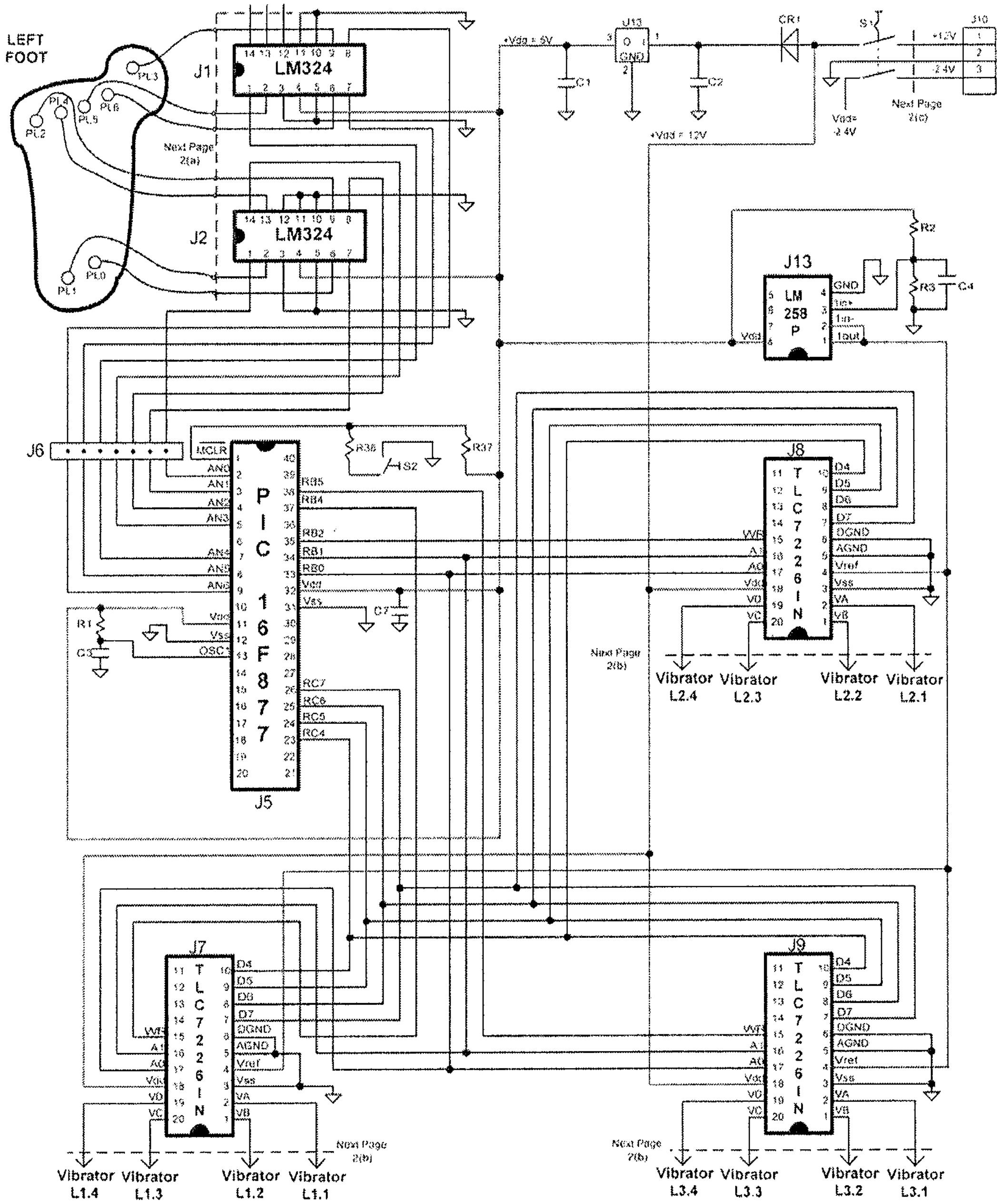


Figure 1. Illustration of sensor, microcontroller device and vibrator arrangement on a human being

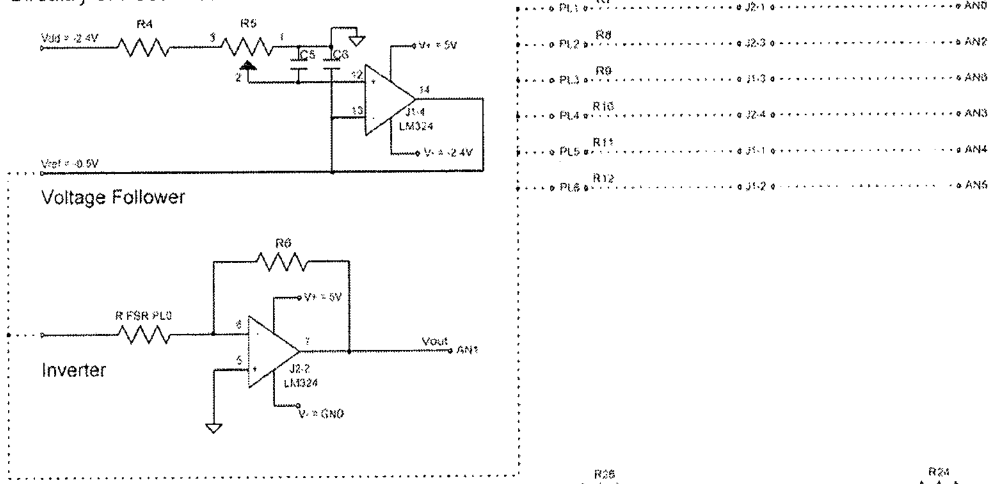
3.1 Device Circuit Concept - Main



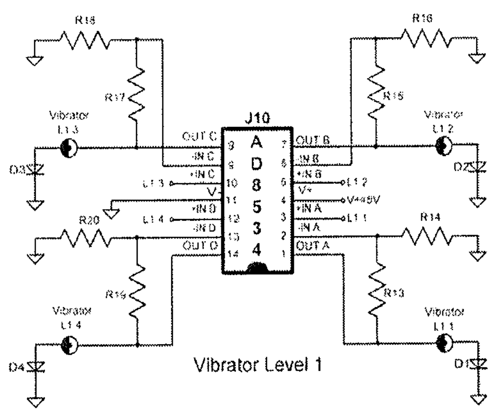
J1 - J2 National Semiconductor , LM324 , Analog Amplifier
J5 Microchip , PIC16F877 , Microcontroller
J6 Data Aquisition Connector
J7 - J9 Texas Instruments , TLC7226IN , 8 Bit 4 Channel D/A Converter
J13 LM258 Analog Anplifier ; S1 Power Switch , S2 Reset Switch
C1 - C2 1 uF , C3 22 pF , C4 , C7 0 1 uF ; CR1 1N4003 , Diode
U13 National Semiconductor LM340T-5.0-ND Voltage Regulator
R1 4 7 K , R2 15 K ; R3 5 K , R37 47K , R38 470

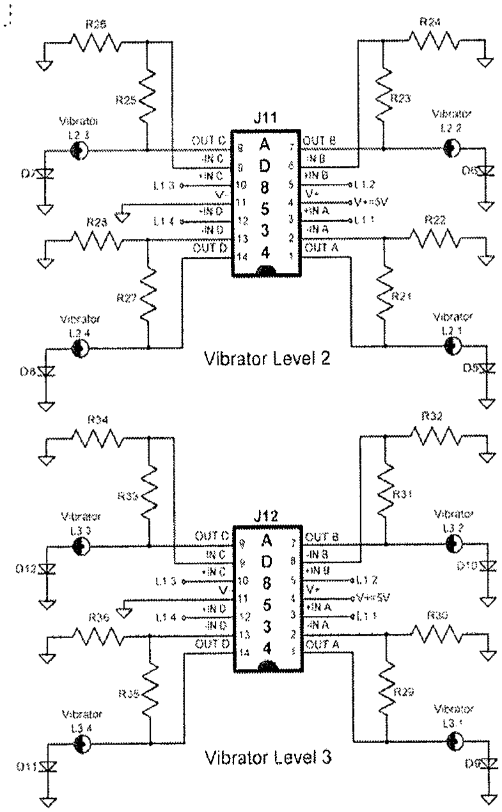
3.2 Device Circuit Concept – Apart

a) Circuitry of Foot Pressure Device

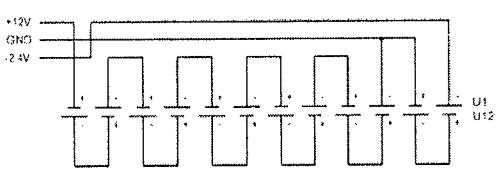


b) Circuitry of Vibratory Feedback Device





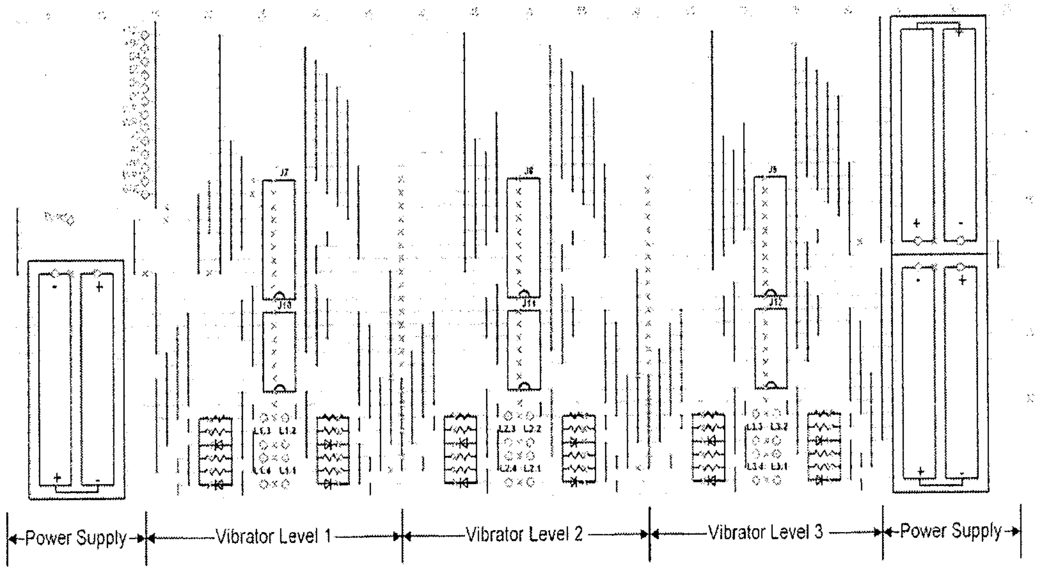
c) Power Supply



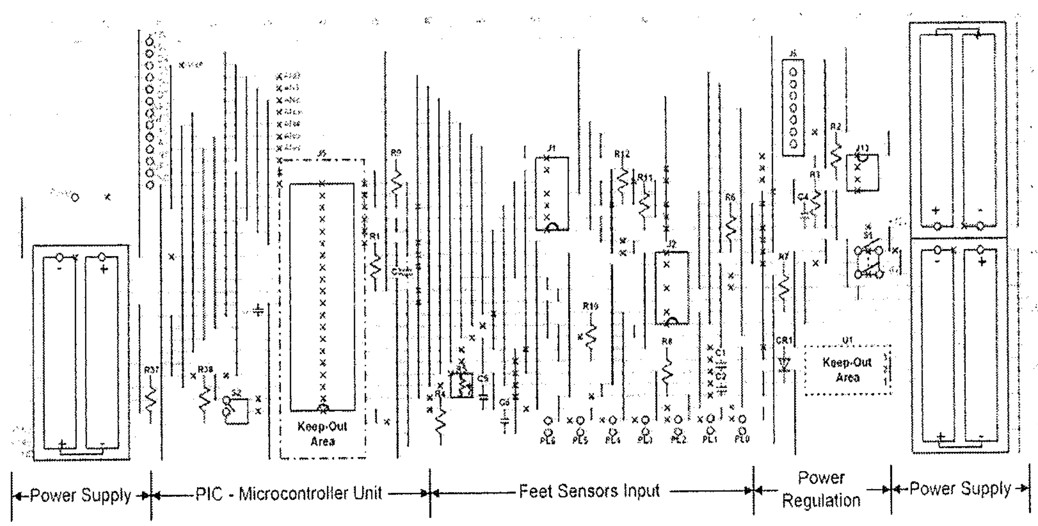
R4 = 22K, R5 = 10K Poti ; R6 - R12 = 33K ; R13 - R36 = 10K
C5 = 0.1uF , C6 = 0.33uF
J1 - J2 LM324 , Analog Ampl. ; J10 - J12 AD8534 , Analog Ampl.

U1 - U12 AAA Size : 1.2 Volt : 550 mA Cap ; NiMH Battery
D1 - D12 Diode

3.3 Circuit Board Design



Board 1 – D/A Conversion; Signal Amplification; Vibrator Output



Board 2 – Microcontroller; Feet Sensors Input; Power Supply

4 Software Design

The main function of the system is it to calculate the deviation from the center of pressure. The vibratory feedback is a direct result of this calculation.
The three parameters for the feedback are :

- Level (1, 2, 3)
- Direction (front, back, left, right)
- Vibration amplitude (1 .. 16)

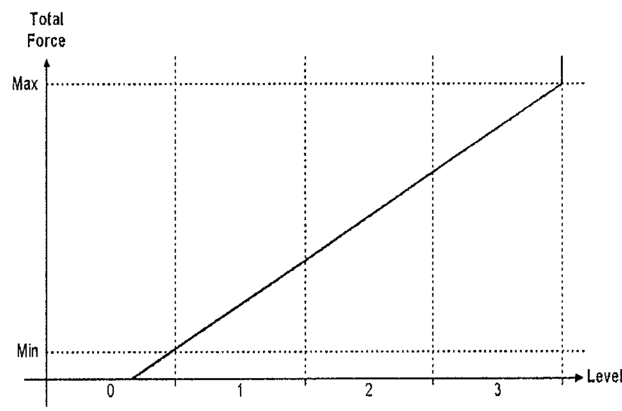


Figure 2 : Feedback Level Distribution

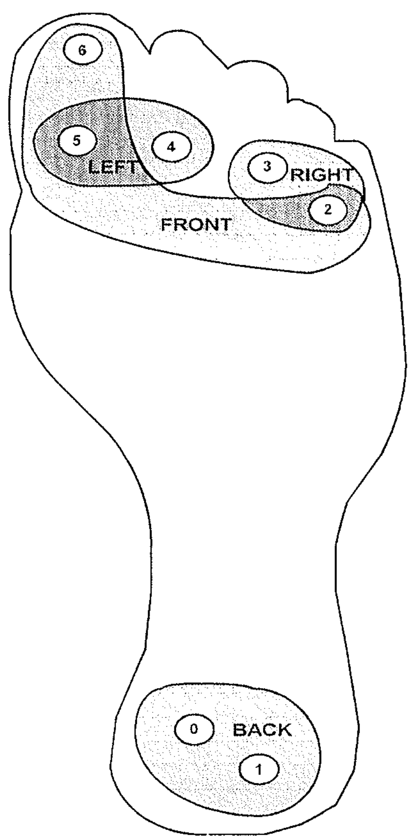
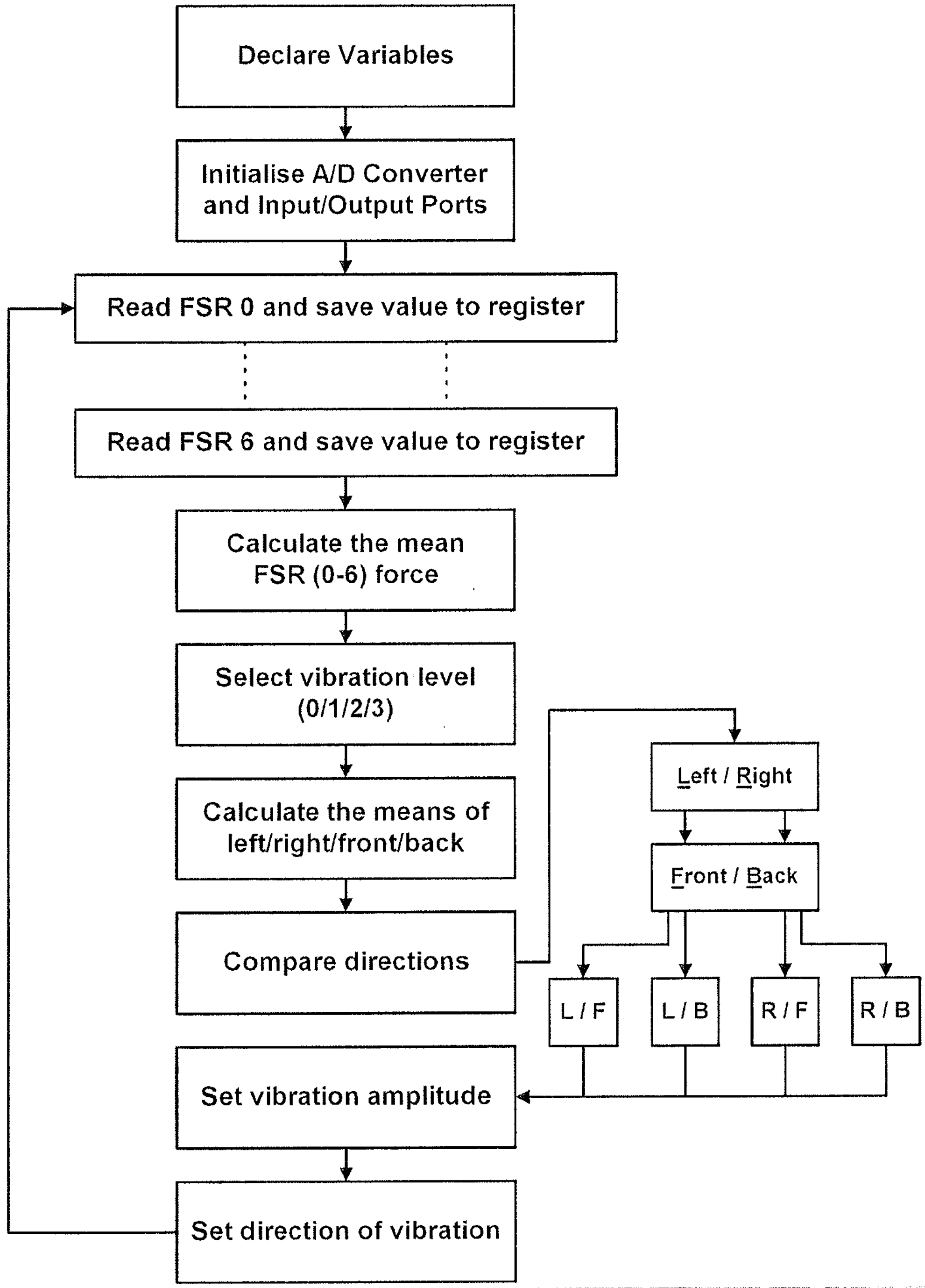


Figure 3 : Force Fields

After the initialization of the microcontroller the assembler program runs in an infinite loop.
This loop starts to read and store the analog values from the 7 FSR's. A mean force was calculated from these values to have one integral force value. This value sets the vibration level depending on the specific thresholds (weight) of the subject. The range goes from Level 0 with no vibration when the foot is not on the ground to Level 3 with the maximum force on the foot (see Figure 2).
Four force fields (see Figure 3) determine the direction of vibration. The program calculates one mean value of every direction and compares it with each other direction. The direction with the highest value "wins".
The vibration amplitude depends on the calculated value in the "winning" field. Now are all three parameters detected, the result can be written to the digital output port on the microcontroller and the loop starts again to read the FSR's.
It is very important to know that only one vibrator runs at the time and there are no differences for the device between the left and the right foot.

4.1 Software Flow Diagram

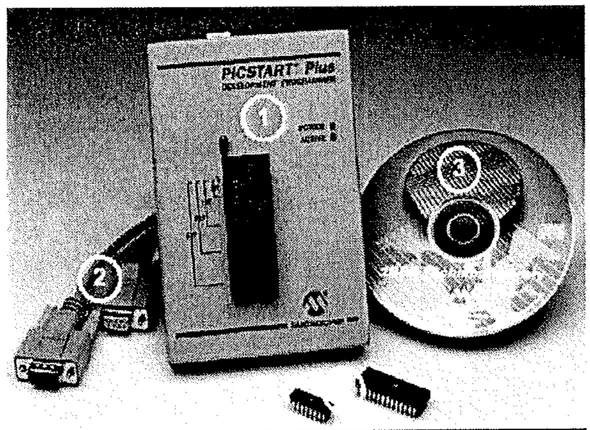


5 Used hardware Components

5.1 PICSTART Plus System

The PICSTART Plus device programmer system consists of the following:

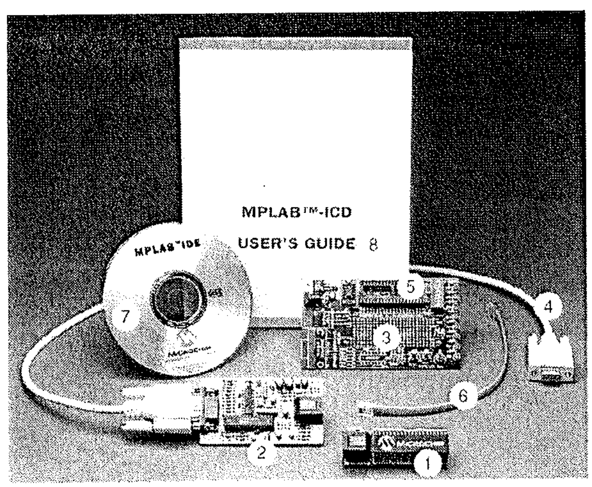
1. PICSTART Plus device programmer
2. RS-232 Interface cable to connect to any standard PC serial port
3. MPLAB IDE software, an Integrated Environment including a text editor, project manager, MPASM assembler, and MPLAB SIM simulator
4. Blank chips for programming



5.2 MPLAB ICD System

The MPLAB ICD Evaluation Kit includes the items listed below

1. The MPLAB ICD Header
2. The MPLAB ICD Module
3. The MPLAB ICD Demo Board
4. RS-232 cable
5. 40-pin DIP and 28-pin SDIP connection sockets
6. 9-inch 6-conductor modular cable
7. CD with complete MPLAB IDE software and documentation
8. Manuals



6 Project "Boston Tea Party"

This project contains the development of a MultiModal Balance Prosthesis by a group of students at the Royal Institute of Technology (KTH) Stockholm. The goal of the proposed project is to integrate, make portable and further develop a device designed to replace inner ear vestibular function and foot pressure sensation. The partner for the vestibular device is Dr. Conrad Wall from the Massachusetts Eye & Ear Infirmary (MEEI). Through several video conferences and a visit of 4 involved students in Boston we discussed the details to integrate the two devices into one system. The project final is scheduled in May 2002.

7 Conclusion and Outlook

The device works excellent and the NMRC will start now to test it on subjects. The most interesting thing to see is, how far the subject can "learn" to understand and to react on the vibratory pattern.
Possible improvements are :

- A higher integration of the circuit
- Circuit to recharge the batteries in the device
- Integrate left and right foot in one device

8 Thanks

At first I want to give many thanks to Professor Lars Oddsson who gave me the opportunity to do my internship at the Neuro Muscular Research Center, Boston University. Peter Meyer has been an important support, many thanks as well for all your ideas. Jens Meyer and everyone at the NMRC for the nice and interesting time.
Many thanks to the "Arbeitskreis Medizintechnik – Hamburg" for the economical support with the scholarship.

9 References

[1] Predko, Myke "Programming and Customizing PICmicro Microcontrollers", McGraw-Hill, 2001
[2] Predko, Myke "PICmicro Microcontroller Pocket Reference", McGraw-Hill, 1999
[3] Katzen, Sid "Quintessential PIC Microcontroller", Springer , 1997
[4] Freding, Mats "Design of artificial sensory system for feet", Master Thesis, 2001
[5] Luca, Carlo De "Open-loop and closed-loop control of posture: A random-walk analysis of center-of-pressure trajectories", Springer , 1993

Exhibit P

Injury Analysis and Prevention Lab Staff meeting notes Sept 19, 2001

- Over the summer I received two grants and a baby boy. Many thanks to everyone for the very nice gifts. One grant from NASA JSC to build BALDERINI, a small BALDER to be used in an obstacle course at JSC. Likely also for Kennedy Space Center. The development of BALDERINI in currently progress with a focus on defining specifications of the device. Also received one grant from Research Retirement Foundation to conduct Swiss ball balance training on healthy elderly individuals. The NIDRR proposal on balance training in elderly fallers was not funded and neither was the NIH proposal on foot pressure sensation and postural control.
- Getting ready to submit and resubmit several papers of BAS pain paper with Carlo and NSBRI gait paper as well as a methods paper with Patrick on Swiss ball training.
- Over the summer we tested a group of vestibular patients on the NSBRI gait perturbation protocol. Nick is in the process of analyzing the data.
- Working with Patrick, Pete and Mukesh, our workstudy student to restore the full integrity of the UMDNJ data base.
- Serge and I went to Natick army research labs to discuss possible future projects and collaboration. I may go to Fort Benning to follow up further but probably not due to current travel circumstances.
- Seminar series for the fall has started. Thanks to Nina for helping out.
- I was contacted by a journalist from New Scientist regarding balance training in the elderly and got an email through Nina and Carlo from Consumer Reports on Swiss Ball balance training.
-
- Peter has had a very busy summer. He had a meeting with his committee yesterday and got a green light to pursue the last experimental phase for his dissertation. He has finished the first experiment, developed the protocol for the second experiment which has included complete foot sole anesthesia and the IRB application, BALDER tweaking for cleaner impulse behavior. He is also working on two manuscripts resulting from the work conducted so far.
- Robert Burgess, spent time in Australia over the summer. He is finishing his data analysis and is writing on his dissertation.

New members in the lab

- I am very happy to introduce Dr. Itzik Meltzer, from the Department of Physical Therapy at Ben Gurion University in Israel our new NIDRR fellow has arrived. We will be working together on the RRF study.
- We have new cluster of Swedish mechatronics students, Mikael and Andreas, who are working with Don and Carlo on the BRP project and Jimmy and Magnus who are working with me on the BALDERINI team. I want to thank Tina for helping out in the visa process.
- We also have a German addition to the group, Eilert Klatte. He will be working with Pete and me on our foot pressure device project.

We have one senior project this year with two students, Stephanie and Dominic. They will test the hypothesis that balance training performed in lying down will improve balance while standing up. They will build a simple device for this and test subjects before and after a period of training in this device.

Injury Analysis and Prevention Lab Staff meeting notes Oct 17, 2001

- Officially started the RRF project as of Oct 1. Worked on the IRB proposal for the RRF proposal. Thanks Serge for being able to review the proposal. Preparing for subject recruitment and instructor recruitment. Itzik has done a great job tracking down possible locations. We have collaborative interest from 2 community centers, one in Brookline and one in Newton.
- Itzik and I met w Dr Silliman regarding the medical screening of the subjects for the study. We also met with Steve Haley and his assistant Jill regarding subject recruitment.
- Next to ready to submit three papers, BAS pain paper with Carlo and NSBRI gait paper as well as a methods paper with Patrick on Swiss ball training. We recruited two elderly subjects for a photoshoot to get new figures for the Swiss ball paper.
- I am working on a poster for NS meeting in San Diego. It's together with Gerry and Dan on his senior project.
- On the grants side I am awaiting the NSBRI announcement as well as a NASA announcement for ground-based studies. Supposed to happen late fall.
- Working on restoring the full integrity of the UMDNJ balance database is progressing with Patrick, Pete and Mukesh, our workstudy student. We are now in the process of entering questionnaire-based data.
- My trip to Fort Benning was put on hold due to effects of Sept 11. I plan to set it up for some time Nov I may go to Fort Benning to follow up further but probably not due to current travel circumstances.
- Seminar series continues. Thanks to Zeynep for hosting in my unplanned absence.

- Itzik has been busy working on the preparation for the RRF study and he is also working on manuscripts and grant proposals for NIDRR pilot studies. He has been very active and successive in contacting directors at the community centers for the RRF study.

- Peter is going full speed ahead on experiments w numbing feet. Four subjects so far, 2 to go. I was a subject last week, very interesting and not painful to inject. ....etc etc. We are lucky to have Michael Bailin helping us in this project. Pete is also working on two papers for his dissertation, one on the iontophoresis method and one on the repeatability of SD parameters. The SD parameters for poster at NS.

- Robert Burgess, spent time in Australia over the summer. He continues to write on his dissertation.

- Nick has mainly been analyzing data from the gait experiments with vestibular patients. He also wrote a routine to simplify protocol design for BALDER experiments.

- Jimmy and Magnus are making progress on the BALDERINI platform. The team has had several meetings over the past month. We have performance specifications nailed down and initial drawings are on the way. Tomorrow we will meet w Leo and Bob from the machine shop to discuss the design. We have decided to use a linear motor as the actuator in the system.

- Eilert Klatte has set up a microprocessor development environment that he will use for his project. He will mainly work on implementing the foot pressure device for gait.

- Our seniors, Dominic and Stephanie are progressing on their project. We will build a small tilted room in the basement for their project. The sense of vertical is very dependent on what we see.

Injury Analysis and Prevention Lab Staff meeting notes Nov 21, 2001

- I worked on the poster for the NS meeting in San Diego. Gerry ended up going. Well-received and some interesting suggestions for further analysis.
- We are continuing the RRF project. IRB was approved. Thanks to Serge for helpful input. After a contact between the BU Risk management office and the JCC insurance company Itzik has started pre-screening subjects.
- Spent time on the BALDERINI project w Jimmy and Magnus. Some very exciting progress. We will run out of funds to completely finish the device, which we knew all along. We are in process to approach NSBRI and ask for supplemental funds.
- On papers, one ms on NSBRI gait data was submitted and two more ms are ready to go. One on LBP EMG and pain is waiting for Carlos final touch and the Balance training methods paper needs a different final ok …
- On the grants side, the NASA announcement for ground-based studies came out. Will submit at least 2 NOI, on BALDERININ continuation and resubmission of rehab proposal to NSBRI.
- Gerry and I met with Casey Kerrigan to discuss collaboration. She has plenty of gait data in patients and the work presented at NS on Linear Synergy should be tested in patients.
- Seminar series approaching end of the semester. I want to thank everyone who helps out incl Nina, Pete and Alex. I currently have two names for the spring semester. Any info about additional candidates is highly appreciated.
- I have been invited to give a seminar at OIOC on Nov 28.
- Met w Tina and all our Swedish visitors to try to solve the reimbursement situation for them. They have run into problems w payroll taking out taxes etc etc etc….tough to learn the US tax system and they should not have to. Thanks to Tina for helping to guide through the mess. We hope to find a better way to solve this for another time.

- Itizik continues to be very active in pursuing the RRF project and it appears to finally pay off. He also worked on two pilot proposals to the Sargent Roybal Center program, one on balance training in chronic stroke patients and one on the implementation of a cost-effective balance training intervention in elderly, Walk&Talk. Interesting concept using the fact that cognitive attention to may degrade motor behavior and balance. We plan to use this as a training stimulus in elderly. He is also working on manuscripts and grant proposals for NIDRR pilot studies.
- Peter has numbed all the feet he needs for his final study and getting ready for final analysis. He went to NS to present the work on repeatability of SD. He is also working on two papers for his dissertation, one on the iontophoresis method and one on the SD parameters.
- Nick continues to analyze data from the gait experiments with vestibular patients. He also worked on a way to extract heel strike information from kinematic data without using any force plate or foot information. Interestingly in turns out that the ap-shank velocity crossing occurs within a few ms of heel strike. Will be very useful for us in the analysis of gait data.
- Jimmy and Magnus are making great progress on the BALDERINI design. We met twice with an automation engineer to discuss different solutions only to realize that we need to build our own implementation of a linear motor. Also met with Leo and Bob from the machine shop to discuss the design so that we can minimize machineshop time. We have finalized the platform design and ordered parts for it. We are alos approaching NSBRI for supplemental funding for components to the device. We knew already initially that the funds provided from NASA would not be sufficient.
- Eilert is making great progress on an updated design of the foot pressure device. .
- Mukesh, our workstudy student is pursuing restoration and integration of the UMDNJ balance database.
- Our seniors, Dominic and Stephanie submitted their project proposals. They started building the tilted room which should be ready in the next week or so.

Injury Analysis and Prevention Lab Staff meeting notes Dec 19, 2001

- Preparing for NASA grant submissions. No or very little money for NSBRI On the grants side, the NASA announcement for ground-based studies came out. Will submit at least 2 NOI, on BALDERININ continuation and resubmission of rehab proposal to NSBRI.
- Gave a well received seminar at OIOC in NY.
- RRF project continuing with great progress. Itzik has recruited and pre-screened 29 subjects. Pre-testing starts next week. He has met with elderly Center in Revere which houses 800 people.
- Spent time on the BALDERINI project w Jimmy and Magnus. They will hold the fort over x-mas start programming using a borrowed motor. Parts in the machine shop being built as we speak. Ordered parts as far as budget allows. Not clear with supplemental budget yet. We are in process to approach NSBRI and ask for supplemental funds.
- On papers, three went out two came back semi accepted/rejected.
- Seminar series ended for this semester Thanks to everyone Nina, Pete, Alex, Jens. NEED NEW NAMES I currently have two names for the spring semester. Any info about additional candidates is highly appreciated.
- I have been invited to give a seminar at OIOC on Nov 28.

- Peter analyzing data, data, data........currently EMG parameters. Progressing well.
- Nick continues to analyze data from the gait experiments with vestibular patients and builds a structured data base of gait data from our experiments.
- Eilert is making great progress on an updated design of the foot pressure device. .
- Our seniors, Dominic and Stephanie submitted their final project proposals. We hope to collect data from tilted room standing in early Jan.

Injury Analysis and Prevention Lab Staff meeting notes Jan 16, 2002

- Working on two NASA grant submissions, BALDERINI continuation and centrifugation/rehab.
- RRF project continuing, training has started and pre-testing almost finished. Itzik testing as we speak.
- BALDERINI project winding-up, Jimmy and Magnus will go home on Jan 21st. They will have a presentation within the next 2 weeks. Andreas and Michael will defend their on Feb 10. We will probably have a video conference for anyone interested.
- Submitted abstract to ISEK with Erik on his dissertation data.
- On papers, resubmitted balance training paper to MSSE as a methods paper. Paper w Josef for J Biomech in press. Other papers on hold at the time due to grant work....
- Seminar series starting up in Feb. I have 5 speakers. Room for a couple more.

- Peter analyzing data and working on two ms.
- Nick building gait data base and also including Erik's data in the same structure.
- Eilert has started programming for the foot pressure device. .
- Our seniors, Dominic and Stephanie are back and need to kick start the proj to get back on pace.

Injury Analysis and Prevention Lab Staff meeting notes Feb 20, 2002

- Submitted two grants to NASA. This made January INSANE!! Hopefully never again.....Thanks to Tina and Nina for help.
- Reviewed a bunch of abstracts for ISEK and working on a couple of IRB proposals.
- On papers, working on response to reviewers of papers with Carlo.
- RRF balance training project is about halfway through for first group of 12 subjects. They are making great progress. I saw them in the beginning and yesterday. I hope we can measure the change we see in these subjects. Patrick is starting up the same training in fallers in Sherbrooke so I have been working w Patrick on a Canadian grant. We may start up a similar program in Israel through Itzik's contacts.
- IP lab is now very empty......Jimmy and Magnus went back home after a great project finish. They demonstrated a functional prototype of BALDERINI, incl sw and hw. We are trying to push all buttons we know of to get the final funding for the project. Conrad has done a lot of ground work on this with NSBRI as well as JSC people. We also had a 20 min visit by Bill Paloski from NASA JSC who was involved in getting use the initial grant for BALDERINI.
- Eilert went back to Germany. Finished designing and building second generation foot pressure device. He did a great job.
- Seminar series started. I want to thank Paolo for an interesting presentation of some of his work.
- Fay Horak will briefly visit us tomorrow. She is involved in one of the NASA grants that I submitted. She has agreed to give us an informal seminar. It will be held in the lounge since the seminar room is uinavailable.
- I may have two new students from KTH available now to work on a thesis project, e.g. BRP....

- Pete submitted his first ms on the Iontophoresis method. He continues to analyze his data and writing on a second ms.
- Nick preparing for next set of experiments for the NSBRI project. Will be conducted together w Ted Raphan from NY, head movements following a-p perturbations.
- Robert is in the final phase of writing up his dissertation.
- Our seniors, Dominic and Stephanie working on tilted room, and device to roll on the floor. They are up for a "reality check" since things don't always work as planned. They are also working on an IRB proposal for the project.

compl19.asm

```
;*****************************************************
;*                                                   *
;*      Artificial Sensory System For Feet           *
;*           NMRC - Boston University                *
;*                                                   *
;*****************************************************
;*
;*      Author :          Eilert Klatte
;*      Version :         0.19
;*      Filename :        COMPL19.ASM
;*      Date :            02/11/2002
;*      Based PIC :       16F877
;*
;*****************************************************
;
;****** CONFIGURATION SWITCHES *********************
;
        list p=16f877
        include "p16f877.inc"
;
;****** DECLARE VARIABLES **************************
;
count   equu    0x20            ;Counter Loop
adtrans equ     0x21            ;A/D result
temp    equ     0x22            ;Variable for temporary use
temp2   equ     0x22            ;Variable for temporary use
adres0  equ     0x23            ;Loop force data of FSR0
adres1  equ     0x24            ;Loop force data of FSR1
adres2  equ     0x25            ;Loop force data of FSR2
adres3  equ     0x26            ;Loop force data of FSR3
adres4  equ     0x27            ;Loop force data of FSR4
adres5  equ     0x28            ;Loop force data of FSR5
adres6  equ     0x29            ;Loop force data of FSR6
adres0r equ     0x2A            ;Shift right of FSR0
adres1r equ     0x2B            ;Shift right of FSR1
adres2r equ     0x2C            ;Shift right of FSR2
adres3r equ     0x2D            ;Shift right of FSR3
adres4r equ     0x2E            ;Shift right of FSR4
adres5r equ     0x2F            ;Shift right of FSR5
adres6r equ     0x30            ;Shift right of FSR6
adsum_l equ     0x31            ;Low-Byte of force mean
adsum_h equ     0x32            ;High-Byte of force mean
mean_l  equ     0x33            ;Mean force value of the left foot area
mean_r  equ     0x34            ;Mean force value of the right foot area
mean_f  equ     0x35            ;Mean force value of the front foot area
mean_fl equ     0x36            ;Part force value of the front foot area
mean_fr equ     0x37            ;Shift Right of front part force
mean_b  equ     0x38            ;Mean force value of the back foot area
;*****************************************************
;*      MAIN PROGRAM DECLARATIONS                    *
;*****************************************************
;
;
        org     0x000           ;Program code starts here
;*****************************************************
;*      SETTINGS                                     *
;*****************************************************
;
iniSTART
        banksel OPTION_REG      ;Bank 1 selected
        movlw   B'10000100'     ;TMR0 prescaler, 1:256
        movwf   OPTION_REG
        clrf    TRISC           ;PORTC all outputs
        clrf    TRISB           ;PORTB all outputs
```

```
        movlw   B'00000000'      ;Left justify , 8 analog channels
        movwf   ADCON1           ;VDD and VSS references
        banksel PORTC            ;Bank 0 selected
        clrf    PORTC            ;Clear PORTC
        call    VIBtl1           ;Latch vibrators in Level 1 with 0 Volt
        call    VIBtl2           ;Latch vibrators in Level 2 with 0 Volt
        call    VIBtl3           ;Latch vibrators in Level 3 with 0 Volt
;*****************************************************
;*      MAIN PROGRAM INFINITE LOOP                   *
;*****************************************************
;
Main
;
;****** READ DATA FROM FSR 0 ***********************
;
        call    Delay            ;1ms time delay
        call    FSRset0          ;Initialise A/D converter to FSR 0
        call    ADconv           ;Get force data from FSR 0
        movf    adtrans, W
        movwf   adres6           ;Move result to adres6
;
;****** READ DATA FROM FSR 1 ***********************
;
        call    Delay            ;1ms time delay
        call    FSRset1          ;Initialise A/D converter to FSR 1
        call    ADconv           ;Get force data from FSR 1
        movf    adtrans, W
        movwf   adres0           ;Move result to adres0
;
;****** READ DATA FROM FSR 2 ***********************
;
        call    Delay            ;1ms time delay
        call    FSRset2          ;Initialise A/D converter to FSR 2
        call    ADconv           ;Get force data from FSR 2
        movf    adtrans, W
        movwf   adres1           ;Move result to adres1
;
;****** READ DATA FROM FSR 3 ***********************
;
        call    Delay            ;1ms time delay
        call    FSRset3          ;Initialise A/D converter to FSR 3
        call    ADconv           ;Get force data from FSR 3
        movf    adtrans, W
        movwf   adres2           ;Move result to adres2
;
;****** READ DATA FROM FSR 4 ***********************
;
        call    Delay            ;1ms time delay
        call    FSRset4          ;Initialise A/D converter to FSR 4
        call    ADconv           ;Get force data from FSR 4
        movf    adtrans, W
        movwf   adres3           ;Move result to adres3
;
;****** READ DATA FROM FSR 5 ***********************
;
        call    Delay            ;1ms time delay
        call    FSRset5          ;Initialise A/D converter to FSR 5
        call    ADconv           ;Get force data from FSR 5
        movf    adtrans, W
        movwf   adres4           ;Move result to adres4
;
;****** READ DATA FROM FSR 6 ***********************
;
```

```
        call    Delay             ;1ms time delay
        call    FSRset6           ;Initialise A/D converter to FSR 6
        call    ADconv            ;Get force data from FSR 6
        movf    adtrans, W
        movwf   adres5            ;Move result to adres5
;
;****** CALL SUBROUTINES ****************************
;
        call    ADDfsr            ;Calculation of the mean FSR force
        call    SIDEmean          ;Side direction mean calculation
        call    LEVselALL         ;Selection of the Vibratory Level
        goto    Main
;***************************************************
;*      START OF THE A/D CONVERSION               *
;***************************************************
;
;
ADconv
        btfss   INTCON,T0IF       ;Wait for Timer0 to timeout
        goto    ADconv            ;Loop till timeout
        bcf     INTCON,T0IF       ;Clear interupt register
        bsf     ADCON0,GO         ;Start A/D conversion
Wait
        btfss   PIR1,ADIF         ;Wait for conversion to complete
        goto    Wait              ;Loop till complete
        movf    ADRESH, W         ;Write A/D result to working register
        movwf   adtrans           ;Move working register to adtrans
        return
;***************************************************
;*      Vibrator Initialising                     *
;***************************************************
;
;
;****** LEVEL 1 ************************************
;
;
VIBset11
        bcf     PORTB,0           ;Select DAC A &
        bcf     PORTB,1           ;Vibrator 1 (Right)
        call    VIBtl1            ;Vibrator transparent/latch Subroutine
        return
VIBset12
        bcf     PORTB,0           ;Select DAC B &
        bsf     PORTB,1           ;Vibrator 2 (Front)
        call    VIBtl1            ;Vibrator transparent/latch Subroutine
        return
VIBset13
        bsf     PORTB,0           ;Select DAC C &
        bcf     PORTB,1           ;Vibrator 3 (Left)
        call    VIBtl1            ;Vibrator transparent/latch Subroutine
        return
VIBset14
        bsf     PORTB,0           ;Select DAC D &
        bsf     PORTB,1           ;Vibrator 4 (Back)
        call    VIBtl1            ;Vibrator transparent/latch Subroutine
        return
;
;****** LEVEL 2 ************************************
;
;
VIBset21
        bcf     PORTB,0           ;Select DAC A &
        bcf     PORTB,1           ;Vibrator 1 (Right)
        call    VIBtl2            ;Vibrator transparent/latch Subroutine
        return
VIBset22
        bcf     PORTB,0           ;Select DAC B &
```

```
        bsf     PORTB,1         ;Vibrator 2 (Front)
        call    VIBtl2          ;Vibrator transparent/latch Subroutine
        return
VIBset23
        bsf     PORTB,0         ;Select DAC C &
        bcf     PORTB,1         ;Vibrator 3 (Left)
        call    VIBtl2          ;Vibrator transparent/latch Subroutine
        return
VIBset24
        bsf     PORTB,0         ;Select DAC D &
        bsf     PORTB,1         ;Vibrator 4 (Back)
        call    VIBtl2          ;Vibrator transparent/latch Subroutine
        return
;
;****** LEVEL 3 ****************************************
;
VIBset31
        bcf     PORTB,0         ;Select DAC A &
        bcf     PORTB,1         ;Vibrator 1 (Right)
        call    VIBtl3          ;Vibrator transparent/latch Subroutine
        return
VIBset32
        bcf     PORTB,0         ;Select DAC B &
        bsf     PORTB,1         ;Vibrator 2 (Front)
        call    VIBtl3          ;Vibrator transparent/latch Subroutine
        return
VIBset33
        bsf     PORTB,0         ;Select DAC C &
        bcf     PORTB,1         ;Vibrator 3 (Left)
        call    VIBtl3          ;Vibrator transparent/latch Subroutine
        return
VIBset34
        bsf     PORTB,0         ;Select DAC D &
        bsf     PORTB,1         ;Vibrator 4 (Back)
        call    VIBtl3          ;Vibrator transparent/latch Subroutine
        return
;*****************************************************
;*      Force Sensing Resistors (FSR) Initialising  *
;*****************************************************
;
FSRset0
        movlw   B'01000001'     ;Fosc/8 , A/D enabled channel AN0
        movwf   ADCON0
        return
FSRset1
        movlw   B'01001001'     ;Fosc/8 , A/D enabled channel AN1
        movwf   ADCON0
        return
FSRset2
        movlw   B'01010001'     ;Fosc/8 , A/D enabled channel AN2
        movwf   ADCON0
        return
FSRset3
        movlw   B'01011001'     ;Fosc/8 , A/D enabled channel AN3
        movwf   ADCON0
        return
FSRset4
        movlw   B'01100001'     ;Fosc/8 , A/D enabled channel AN4
        movwf   ADCON0
        return
FSRset5
        movlw   B'01101001'     ;Fosc/8 , A/D enabled channel AN5
        movwf   ADCON0
```

```
        return
FSRset6
        movlw   B'01110001'      ;Fosc/8 , A/D enabled channel AN6
        movwf   ADCON0
        return
;****************************************************
;*      Vibrator transparent/latch Subroutines     *
;****************************************************
;
VIBtl1
        bcf     PORTB,4          ;Transparent mode for vibrators in Level 1
        bsf     PORTB,4          ;Latch mode with actual voltage
        return
VIBtl2
        bcf     PORTB,2          ;Transparent mode for vibrators in Level 2
        bsf     PORTB,2          ;Latch mode with actual voltage
        return
VIBtl3
        bcf     PORTB,5          ;Transparent mode for vibrators in Level 3
        bsf     PORTB,5          ;Latch mode with actual voltage
        return
;****************************************************
;*      Time Delay Subroutine                      *
;****************************************************
;
Delay
        movwf   count
DelayLoop
        nop
        nop
        nop
        nop
        nop
        nop
        decfsz  count, f
        goto    DelayLoop
        return
;****************************************************
;*      Select Vibrating Amplitude                 *
;****************************************************
;
ADsub
;
;****** VIBRATION MODE 10 ***************************
;
        movlw   d'230'           ;Set trigger level to maximum
        subwf   adtrans, W       ;Compare trigger level with A/D value
        movf    STATUS, W
        movwf   temp
        btfsc   temp, 0          ;Test Carry-Bit, Skip if adtrans lower-
        call    VIBmode10        ;than trigger level
        btfsc   temp, 0          ;Return if VIBmode is set
        return                   ;Back to COP comparison
;
;****** VIBRATION MODE 9 ****************************
;
        movlw   d'215'           ;Set trigger level
        subwf   adtrans, W       ;Compare trigger level with A/D value
        movf    STATUS, W
        movwf   temp
        btfsc   temp, 0          ;Test Carry-Bit, Skip if adtrans lower-
        call    VIBmode9         ;than trigger level
        btfsc   temp, 0          ;Return if VIBmode is set
```

```
        return                          ;Back to COP comparison
;
;****** VIBRATION MODE 8 ****************************
;
        movlw   d'200'                  ;Set trigger level
        subwf   adtrans, W              ;Compare trigger level with A/D value
        movf    STATUS, W
        movwf   temp
        btfsc   temp, 0                 ;Test Carry-Bit, Skip if adtrans lower-
        call    VIBmode8                ;than trigger level
        btfsc   temp, 0                 ;Return if VIBmode is set
        return                          ;Back to COP comparison
;
;****** VIBRATION MODE 7 ****************************
;
        movlw   d'180'                  ;Set trigger level
        subwf   adtrans, W              ;Compare trigger level with A/D value
        movf    STATUS, W
        movwf   temp
        btfsc   temp, 0                 ;Test Carry-Bit, Skip if adtrans lower-
        call    VIBmode7                ;than trigger level
        btfsc   temp, 0                 ;Return if VIBmode is set
        return                          ;Back to COP comparison
;
;****** VIBRATION MODE 6 ****************************
;
        movlw   d'155'                  ;Set trigger level
        subwf   adtrans, W              ;Compare trigger level with A/D value
        movf    STATUS, W
        movwf   temp
        btfsc   temp, 0                 ;Test Carry-Bit, Skip if adtrans lower-
        call    VIBmode6                ;than trigger level
        btfsc   temp, 0                 ;Return if VIBmode is set
        return                          ;Back to COP comparison
;
;****** VIBRATION MODE 5 ****************************
;
        movlw   d'130'                  ;Set trigger level
        subwf   adtrans, W              ;Compare trigger level with A/D value
        movf    STATUS, W
        movwf   temp
        btfsc   temp, 0                 ;Test Carry-Bit, Skip if adtrans lower-
        call    VIBmode5                ;than trigger level
        btfsc   temp, 0                 ;Return if VIBmode is set
        return                          ;Back to COP comparison
;
;****** VIBRATION MODE 4 ****************************
;
        movlw   d'105'                  ;Set trigger level
        subwf   adtrans, W              ;Compare trigger level with A/D value
        movf    STATUS, W
        movwf   temp
        btfsc   temp, 0                 ;Test Carry-Bit, Skip if adtrans lower-
        call    VIBmode4                ;than trigger level
        btfsc   temp, 0                 ;Return if VIBmode is set
        return                          ;Back to COP comparison
;
;****** VIBRATION MODE 3 ****************************
;
        movlw   d'80'                   ;Set trigger level
        subwf   adtrans, W              ;Compare trigger level with A/D value
        movf    STATUS, W
        movwf   temp
```

```
        btfsc   temp, 0            ;Test Carry-Bit, Skip if adtrans lower-
        call    VIBmode3           ;than trigger level
        btfsc   temp, 0            ;Return if VIBmode is set
        return                     ;Back to COP comparison
;
;****** VIBRATION MODE 2 ****************************
;
        movlw   d'55'              ;Set trigger level
        subwf   adtrans, W         ;Compare trigger level with A/D value
        movf    STATUS, W
        movwf   temp
        btfsc   temp, 0            ;Test Carry-Bit, Skip if adtrans lower-
        call    VIBmode2           ;than trigger level
        btfsc   temp, 0            ;Return if VIBmode is set
        return                     ;Back to COP comparison
;
;****** VIBRATION MODE 1 ****************************
;
        movlw   d'30'              ;Set trigger level to minimum
        subwf   adtrans, W         ;Compare trigger level with A/D value
        movf    STATUS, W
        movwf   temp
        btfsc   temp, 0            ;Test Carry-Bit, Skip if adtrans lower-
        call    VIBmode1           ;than trigger level
        btfsc   temp, 0            ;Return if VIBmode is set
        return                     ;Back to COP comparison
;
;****** VIBRATION MODE 0 ****************************
;
        call    VIBmode0           ;No vibration
        return
VIBmode0
        movlw   b'00000000'
        movwf   PORTC              ;Clear PORT C
        return
VIBmode1
        movlw   b'01100000'
        movwf   PORTC              ;Lowest vibration mode on PORT C
        return
VIBmode2
        movlw   b'01110000'
        movwf   PORTC              ;Vibration mode 2 on PORT C
        return
VIBmode3
        movlw   b'10000000'
        movwf   PORTC              ;Vibration mode 3 on PORT C
        return
VIBmode4
        movlw   b'10010000'
        movwf   PORTC              ;Vibration mode 4 on PORT C
        return
VIBmode5
        movlw   b'10100000'
        movwf   PORTC              ;Vibration mode 5 on PORT C
        return
VIBmode6
        movlw   b'10110000'
        movwf   PORTC              ;Vibration mode 6 on PORT C
        return
VIBmode7
        movlw   b'11000000'
        movwf   PORTC              ;Vibration mode 7 on PORT C
        return
```

```
VIBmode8
        movlw   b'11010000'
        movwf   PORTC              ;Vibration mode 8 on PORT C
        return
VIBmode9
        movlw   b'11100000'
        movwf   PORTC              ;Vibration mode 9 on PORT C
        return
VIBmode10
        movlw   b'11110000'
        movwf   PORTC              ;Vibration mode 10 on PORT C
        return
;*****************************************************
;*      CALCULATION OF THE MEAN FSR FORCE           *
;*****************************************************
;
;
ADDfsr
        clrf    adsum_l            ;Initiate adsum_l
        clrf    adsum_h            ;Initiate adsum_h
        movlw   D'0'               ;Add Constant Value to Compensate-
        movwf   adsum_l            ;differnent subject weight
        movf    adres0, W
        addwf   adres1, W          ;Addition of adres0 and adres1
        movwf   adsum_l            ;Result in adsum_l
        btfsc   STATUS, 0          ;Carry-Flag test
        incf    adsum_h, F         ;Increment adsum if Carry-Flag =1
        movf    adsum_l, W
        addwf   adres2, W          ;Addition of adsum_l and adres2
        movwf   adsum_l            ;Result in adsum_l
        btfsc   STATUS, 0          ;Carry-Flag test
        incf    adsum_h, F         ;Increment adsum if Carry-Flag =1
        movf    adsum_l, W
        addwf   adres3, W          ;Addition of adsum_l and adres3
        movwf   adsum_l            ;Result in adsum_l
        btfsc   STATUS, 0          ;Carry-Flag test
        incf    adsum_h, F         ;Increment adsum if Carry-Flag =1
        movf    adsum_l, W
        addwf   adres4, W          ;Addition of adsum_l and adres4
        movwf   adsum_l            ;Result in adsum_l
        btfsc   STATUS, 0          ;Carry-Flag test
        incf    adsum_h, F         ;Increment adsum if Carry-Flag =1
        movf    adsum_l, W
        addwf   adres5, W          ;Addition of adsum_l and adres5
        movwf   adsum_l            ;Result in adsum_l
        btfsc   STATUS, 0          ;Carry-Flag test
        incf    adsum_h, F         ;Increment adsum if Carry-Flag =1
        movf    adsum_l, W
        addwf   adres6, W          ;Addition of adsum_l and adres6
        movwf   adsum_l            ;Result in adsum_l
        btfsc   STATUS, 0          ;Carry-Flag test
        incf    adsum_h, F         ;Increment adsum if Carry-Flag =1
        return                     ;Return to Main Program Loop
;*****************************************************
;*      SELECTION OF THE VIBRATORY LEVEL            *
;*****************************************************
;
;
;
;****** FUNCTION OF adsum_h ************************
;
;       BIT1    BIT0    LEVEL
;       0       0       0
;       0       1       1
;       1       0       2
```

```
;        1        1        3
;
LEVselALL
        btfss   adsum_h, 0          ;Select Level 0/2 or 1/3
        goto    LEVsel02
        btfss   adsum_h, 1          ;Subroutine Level 1 or 3
        goto    SIDE1
        goto    SIDE3
LEVsel02
        btfss   adsum_h, 1          ;Subroutine Level 0 or 2
        goto    SIDE0
        goto    SIDE2
SIDE0                               ;Not enough force - no virbation
        call    VIBmode0            ;Set vibration amplitude to zero
        call    VIBset11
        call    VIBset21
        call    VIBset31
        call    VIBset12
        call    VIBset22
        call    VIBset32
        call    VIBset13
        call    VIBset23
        call    VIBset33
        call    VIBset14
        call    VIBset24
        call    VIBset34
        return                      ;Return to Main Program Loop
SIDE1
        call    SIDEcomp            ;Side comparison for Level 1
        btfss   temp2, 0
        goto    SIDE1_13
SIDE1_24
        btfss   temp2, 1
        goto    SIDE1_2
SIDE1_4
        call    VIBset14
        call    VIBmode0
        call    VIBset11
        call    VIBset21
        call    VIBset31
        call    VIBset12
        call    VIBset22
        call    VIBset32
        call    VIBset13
        call    VIBset23
        call    VIBset33
        call    VIBset24
        call    VIBset34
        return                      ;Return to Main Program Loop
SIDE1_2
        call    VIBset12
        call    VIBmode0
        call    VIBset11
        call    VIBset21
        call    VIBset31
        call    VIBset22
        call    VIBset32
        call    VIBset13
        call    VIBset23
        call    VIBset33
        call    VIBset14
        call    VIBset24
        call    VIBset34
```

```
        return                          ;Return to Main Program Loop
SIDE1_13
        btfss   temp2, 1
        goto    SIDE1_1
SIDE1_3
        call    VIBset13
        call    VIBmode0
        call    VIBset11
        call    VIBset21
        call    VIBset31
        call    VIBset12
        call    VIBset22
        call    VIBset32
        call    VIBset23
        call    VIBset33
        call    VIBset14
        call    VIBset24
        call    VIBset34
        return                          ;Return to Main Program Loop
SIDE1_1
        call    VIBset11
        call    VIBmode0
        call    VIBset21
        call    VIBset31
        call    VIBset12
        call    VIBset22
        call    VIBset32
        call    VIBset13
        call    VIBset23
        call    VIBset33
        call    VIBset14
        call    VIBset24
        call    VIBset34
        return                          ;Return to Main Program Loop
SIDE2
        call    SIDEcomp                ;Side comparison for Level 2
        btfss   temp2, 0
        goto    SIDE2_13
SIDE2_24
        btfss   temp2, 1
        goto    SIDE2_2
SIDE2_4
        call    VIBset24
        call    VIBmode0
        call    VIBset11
        call    VIBset21
        call    VIBset31
        call    VIBset12
        call    VIBset22
        call    VIBset32
        call    VIBset13
        call    VIBset23
        call    VIBset33
        call    VIBset14
        call    VIBset34
        return                          ;Return to Main Program Loop
SIDE2_2
        call    VIBset22
        call    VIBmode0
        call    VIBset11
        call    VIBset21
        call    VIBset31
        call    VIBset12
```

```
        call    VIBset32
        call    VIBset13
        call    VIBset23
        call    VIBset33
        call    VIBset14
        call    VIBset24
        call    VIBset34
        return                  ;Return to Main Program Loop
SIDE2_13
        btfss   temp2, 1
        goto    SIDE2_1
SIDE2_3
        call    VIBset23
        call    VIBmode0
        call    VIBset11
        call    VIBset21
        call    VIBset31
        call    VIBset12
        call    VIBset22
        call    VIBset32
        call    VIBset13
        call    VIBset33
        call    VIBset14
        call    VIBset24
        call    VIBset34
        return                  ;Return to Main Program Loop
SIDE2_1
        call    VIBset21
        call    VIBmode0
        call    VIBset11
        call    VIBset31
        call    VIBset12
        call    VIBset22
        call    VIBset32
        call    VIBset13
        call    VIBset23
        call    VIBset33
        call    VIBset14
        call    VIBset24
        call    VIBset34
        return                  ;Return to Main Program Loop
SIDE3
        call    SIDEcomp        ;Side comparison for Level 3
        btfss   temp2, 0
        goto    SIDE3_13
SIDE3_24
        btfss   temp2, 1
        goto    SIDE3_2
SIDE3_4
        call    VIBset34
        call    VIBmode0
        call    VIBset11
        call    VIBset21
        call    VIBset31
        call    VIBset12
        call    VIBset22
        call    VIBset32
        call    VIBset13
        call    VIBset23
        call    VIBset33
        call    VIBset14
        call    VIBset24
        return                  ;Return to Main Program Loop
```

```
SIDE3_2
        call    VIBset32
        call    VIBmode0
        call    VIBset11
        call    VIBset21
        call    VIBset31
        call    VIBset12
        call    VIBset22
        call    VIBset13
        call    VIBset23
        call    VIBset33
        call    VIBset14
        call    VIBset24
        call    VIBset34
        return                  ;Return to Main Program Loop
SIDE3_13
        btfss   temp2, 1
        goto    SIDE3_1
SIDE3_3
        call    VIBset33
        call    VIBmode0
        call    VIBset11
        call    VIBset21
        call    VIBset31
        call    VIBset12
        call    VIBset22
        call    VIBset32
        call    VIBset13
        call    VIBset23
        call    VIBset14
        call    VIBset24
        call    VIBset34
        return                  ;Return to Main Program Loop
SIDE3_1
        call    VIBset31
        call    VIBmode0
        call    VIBset11
        call    VIBset21
        call    VIBset12
        call    VIBset22
        call    VIBset32
        call    VIBset13
        call    VIBset23
        call    VIBset33
        call    VIBset14
        call    VIBset24
        call    VIBset34
        return                  ;Return to Main Program Loop
;*****************************************************
;*      SIDE DIRECTION MEAN                           *
;*****************************************************
;
SIDEmean
;
;****** Left ****************************************
;
        bcf     STATUS, 0
        rrf     adres5, W
        movwf   adres5r
        bcf     STATUS, 0
        rrf     adres4, W
        movwf   adres4r
        movfw   adres4r
```

```
        addwf   adres5r, W
        movwf   mean_l
;
;****** Right ****************************************
;
        bcf     STATUS, 0
        rrf     adres3, W
        movwf   adres3r
        bcf     STATUS, 0
        rrf     adres2, W
        movwf   adres2r
        movfw   adres2r
        addwf   adres3r, W
        movwf   mean_r
;
;****** Front ****************************************
;
        bcf     STATUS, 0
        rrf     adres5, W
        movwf   adres5r
        bcf     STATUS, 0
        rrf     adres2, W
        movwf   adres2r
        movfw   adres2r
        addwf   adres5r, W
        movwf   mean_f1
        bcf     STATUS, 0
        rrf     adres6, W
        movwf   adres6r
        bcf     STATUS, 0
        rrf     mean_f1, W
        movwf   mean_fr
        movfw   mean_fr
        addwf   adres6r, W
        movwf   mean_f
;
;****** Back *****************************************
;
        bcf     STATUS, 0
        rrf     adres1, W
        movwf   adres1r
        bcf     STATUS, 0
        rrf     adres0, W
        movwf   adres0r
        movfw   adres0r
        addwf   adres1r, W
        movwf   mean_b
        return
;****************************************************
;*      SIDE COMPARISON                             *
;****************************************************
;
SIDEcomp
        movf    mean_r, W
        subwf   mean_l, W
        movf    STATUS, W
        movwf   temp
        btfss   temp, 0
        goto    COMP_r
COMP_l
        call    COMP_fb
        btfss   temp, 0
        goto    COMP_lf
```

```
        goto    COMP_lb
COMP_r
        call    COMP_fb
        btfss   temp, 0
        goto    COMP_rf
        goto    COMP_rb
COMP_fb
        movf    mean_f, W
        subwf   mean_b, W
        movf    STATUS, W
        movwf   temp
        return
COMP_lf
        movf    mean_l, W
        subwf   mean_f, W
        movf    STATUS, W
        movwf   temp
        btfss   temp, 0
        goto    SET_l
        goto    SET_f
COMP_lb
        movf    mean_l, W
        subwf   mean_b, W
        movf    STATUS, W
        movwf   temp
        btfss   temp, 0
        goto    SET_l
        goto    SET_b
COMP_rf
        movf    mean_r, W
        subwf   mean_f, W
        movf    STATUS, W
        movwf   temp
        btfss   temp, 0
        goto    SET_r
        goto    SET_f
COMP_rb
        movf    mean_r, W
        subwf   mean_b, W
        movf    STATUS, W
        movwf   temp
        btfss   temp, 0
        goto    SET_r
        goto    SET_b
SET_r
        movf    mean_r, W
        movwf   adtrans
        call    ADsub
        bcf     temp2, 0        ;LSB of temp2 : 00
        bcf     temp2, 1        ;Right vibrator is set
        return
SET_l
        movf    mean_l, W
        movwf   adtrans
        call    ADsub
        bcf     temp2, 0        ;LSB of temp2 : 10
        bsf     temp2, 1        ;Left vibrator is set
        return
SET_f
        movf    mean_f, W
        movwf   adtrans
        call    ADsub
        bsf     temp2, 0        ;LSB of temp2 : 01
```

```
        bcf     temp2, 1            ;Front vibrator is set
        return
SET_b
        movf    mean_b, W
        movwf   adtrans
        call    ADsub
        bsf     temp2, 0            ;LSB of temp2 : 11
        bsf     temp2, 1            ;Back vibrator is set
        return

        end
```